New Jersey Office of the Attorney General

Division of Consumer Affairs
New Jersey Board of Pharmacy
Statutes and Regulations

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BOARD OF PHARMACY

CHAPTER 1. GENERAL PROVISIONS

45:1–1. Persons entitled to practice, etc. under former laws unaffected

Any person now entitled to practice any profession or to engage in any occupation, governed or regulated by the provisions of this title by virtue of any prior law, shall continue to be entitled to practice or engage in the same, notwithstanding the enactment of this title, and the validity of any license or other authorization to practice any such profession or to engage in any such occupation, heretofore issued to any person under any prior law, or of any proceeding pending to obtain such a license or authorization shall not be affected by the enactment of this title but all such persons shall in all other respects be subject to the provisions of this title.

45:1–2. Repealed by L.1971, c. 60, § 5, eff. March 25, 1971

45:1–2.1. Professional boards and commissions; application of act

The provisions of this act shall apply to the following boards and commissions: the New Jersey State Board of Accountancy, the New Jersey State Board of Architects, the New Jersey State Board of Cosmetology and Hairstyling, the Board of Examiners of Electrical Contractors, the New Jersey State Board of Dentistry, the State Board of Mortuary Science of New Jersey, the State Board of Professional Engineers and Land Surveyors, the State Board of Marriage and Family Therapy Examiners, the State Board of Medical Examiners, the New Jersey Board of Nursing, the New Jersey State Board of Optometrists, the State Board of Examiners of Ophthalmic Dispensers and Ophthalmic Technicians, the Board of Pharmacy, the State Board of Professional Planners, the State Board of Psychological Examiners, the State Board of Examiners of Master Plumbers, the New Jersey Real Estate Commission, the State Board of Shorthand Reporting, the State Board of Veterinary Medical Examiners, the Radiologic Technology Board of Examiners, the Acupuncture Examining Board, the State Board of Chiropractic Examiners, the State Board of Respiratory Care, the State Real Estate Appraiser Board, the State Board of Social Work Examiners, the State Board of Public Movers and Warehousemen and the State Board of Physical Therapy Examiners.

45:1–2.2. Appointment of members by governor; public members; member from department in executive branch; quorum; vote necessary for action

a. All members of the several professional boards and commissions shall be appointed by the Governor in the manner prescribed by law; except in appointing members other than those appointed pursuant to subsection b. or subsection c., the Governor shall give due consideration to, but shall not be bound by, recommendations submitted by the appropriate professional organizations of this State.

b. In addition to the membership otherwise prescribed by law, the Governor shall appoint in the same manner as presently prescribed by law for the appointment of members, two additional members to represent the interests of the public, to be known as public members, to each of the following boards and commissions: The New Jersey State Board of Accountancy, the New Jersey State Board of Architects, the New Jersey State Board of Cosmetology and Hairstyling, the New Jersey State Board of Dentistry, the State Board of Mortuary Science of New Jersey, the State Board of Professional Engineers and Land Surveyors, the State Board of Medical Examiners, the New Jersey Board of Nursing, the New Jersey State Board of Optometrists, the State Board of Examiners of Ophthalmic Dispensers and Ophthalmic Technicians, the Board of

Pharmacy, the State Board of Professional Planners, the State Board of Psychological Examiners, the New Jersey Real Estate Commission, the State Board of Shorthand Reporting, the State Board of Social Work Examiners, and the State Board of Veterinary Medical Examiners, and one additional public member to each of the following boards: the Board of Examiners of Electrical Contractors, the State Board of Marriage and Family Therapy Examiners, the State Board of Examiners of Master Plumbers, and the State Real Estate Appraiser Board. Each public member shall be appointed for the term prescribed for the other members of the board or commission and until the appointment of his successor. Vacancies shall be filled for the unexpired term only. The Governor may remove any such public member after hearing, for misconduct, incompetency, neglect of duty or for any other sufficient cause.

No public member appointed pursuant to this section shall have any association or relationship with the profession or a member thereof regulated by the board of which he is a member, where such association or relationship would prevent such public member from representing the interest of the public. Such a relationship includes a relationship with members of one's immediate family; and such association includes membership in the profession regulated by the board. To receive services rendered in a customary client relationship will not preclude a prospective public member from appointment. This paragraph shall not apply to individuals who are public members of boards on the effective date of this act.

It shall be the responsibility of the Attorney General to insure that no person with the aforementioned association or relationship or any other questionable or potential conflict of interest shall be appointed to serve as a public member of any board regulated by this section. Where a board is required to examine the academic and professional credentials of an applicant for licensure or to test such applicant orally, no public member appointed pursuant to this section shall participate in such examination process; provided, however, that public members shall be given notice of and may be present at all such examination processes and deliberations concerning the results thereof, and, provided further, that public members may participate in the development and establishment of the procedures and criteria for such examination processes.

c. The Governor shall designate a department in the Executive Branch of the State Government which is closely related to the profession or occupation regulated by each of the boards or commissions designated in section 1 of P.L.1971, c. 60 (C. 45:1–2.1) and shall appoint the head of such department, or the holder of a designated office or position in such department, to serve without compensation at the pleasure of the Governor as a member of such board or commission.

d. A majority of the voting members of such boards or commissions shall constitute a quorum thereof and no action of any such board or commission shall be taken except upon the affirmative vote of a majority of the members of the entire board or commission.

45:1–2.3. Qualifications; rights and duties

Such additional members:

a. Need not meet the educational and professional requirements for membership on such boards or commissions as provided in the several statutes establishing such boards and commissions; and

b. Shall be voting members subject to the same rights, obligations and duties as other members of their respective boards or commissions.

45:1–2.4. Effect of act on term of member in office

Nothing in this act shall affect the right of a board or commission member in office on the effective date of this act to continue to serve for the term for which he was appointed..

45:1–2.5. Compensation and reimbursement of expenses of members; executive secretaries; compensation and terms of employment; offices and meeting places

With respect to the boards or commissions designated in section 1 of P.L.1971, c. 60 (C.45:1–2.1), except as otherwise provided in subsection d. of this section, and notwithstanding the provisions of any other law:

a. The officers and members shall be compensated on a per diem basis in the amount of $25.00 or an amount to be determined by the Attorney General, with the approval of the State Treasurer, but not to exceed $100.00 per diem or $2,500.00 annually, and shall be reimbursed for actual expenses reasonably incurred in the performance of their official duties. Such moneys shall be paid according to rules and regulations promulgated by the Attorney General.

b. The executive secretary shall receive such salary as shall be determined by the appointing authority within the limits of available appropriations and shall serve at its pleasure. Any such executive secretary who holds a certificate, license or registration issued by the board or commission by which he is employed shall not during such employment be permitted to engage in any profession or occupation regulated by the board or commission.

c. The head of the department to which such board or commission is assigned shall maintain within any public building, whether owned or leased by the State, suitable quarters for the board's or commission's office and meeting place, provided that no such office or meeting place shall be within premises owned or occupied by an officer or member of such board or commission.

d. The compensation schedule for members of boards and commissions provided in subsection a. of this section shall not apply to the members of the New Jersey Real Estate Commission, who shall be compensated pursuant to R.S.45:15–6 or to members of the State Board of Medical Examiners who shall receive compensation of $150 per diem.

45:1–2.6. Inapplicability of act to rights under civil service or any pension law or retirement system

Nothing in this act shall deprive any person of any tenure rights or of any right or protection provided him by Title 11 of the Revised Statutes, Civil Service,[1] or any pension law or retirement system.

[1]*Now title 11A.*

45:1–3. Expenses of boards paid from income; surplus paid to state treasurer; accounts

Each member of the boards mentioned in section 45:1–2 [1] of this title shall be entitled to his actual traveling and other expenses incurred in the performance of his duties, which sum shall be paid from the license fees and other sources of income of such boards. Such boards shall also be entitled to expend from their income such sums as shall be necessary to defray all proper expenses incurred by them in the performance of their duties, including the compensation of any of their officers or agents whom they are authorized to compensate. Such boards, if authorized to collect an annual registration or license fee from persons licensed by them, may retain in their treasuries the fees so collected and use the same for the purpose of defraying the expenses of securing evidence against and prosecuting persons violating the provisions of the laws with the enforcement ofwhich they are charged, or, in case

the revenue of the boards from other sources shall be insufficient to pay the salary of their secretaries and their other expenses, such fees may be expended for such purposes. Such boards shall be entitled to retain, in addition to the above, at least one hundred dollars in their treasuries for the purpose of preparing and holding their examinations. On or before October thirty-first in each year such boards shall pay to the state treasurer all moneys remaining in their treasuries, except as above stated, which sum, when so paid, shall form a part of the state fund. Such boards shall keep accurate accounts of their receipts and expenditures, which accounts shall be subject to audit by the state comptroller.

[1]*Repealed; see, now, §§ 45:1–2.1, 45:1–2.2.*

45:1–3.1. Application of act

The provisions of this act shall apply to the following boards and commissions: the New Jersey State Board of Accountancy, the New Jersey State Board of Architects, the New Jersey State Board of Cosmetology and Hairstyling, the Board of Examiners of Electrical Contractors, the New Jersey State Board of Dentistry, the State Board of Mortuary Science of New Jersey, the State Board of Professional Engineers and Land Surveyors, the State Board of Marriage and Family Therapy Examiners, the State Board of Medical Examiners, the New Jersey Board of Nursing, the New Jersey State Board of Optometrists, the State Board of Examiners of Ophthalmic Dispensers and Ophthalmic Technicians, the Board of Pharmacy, the State Board of Professional Planners, the State Board of Psychological Examiners, the State Board of Examiners of Master Plumbers, the State Board of Shorthand Reporting, the State Board of Veterinary Medical Examiners, the Radiologic Technology Board of Examiners, the Acupuncture Examining Board, the State Board of Chiropractic Examiners, the State Board of Respiratory Care, the State Real Estate Appraiser Board , the New Jersey Cemetery Board, the State Board of Social Work Examiners and the State Board of Physical Therapy Examiners.

45:1–3.2. Charges for examinations, licensures and other services; establishment or change by rule; standards

Notwithstanding the provisions of Title 45 of the Revised Statutes or any other law to the contrary, any board or commission named in section 1 of this supplementary act [1] may by rule establish, prescribe or change the charges for examinations, licensures and other services it performs, which rule shall first be approved by the head of the department to which such board or commission is assigned and shall be adopted in accordance with the provisions of the ''Administrative Procedure Act,'' P.L.1968, c. 410 (C. 52:14B–1).

Any board's or commission's charges established, prescribed or changed pursuant to this section shall be established, prescribed or changed to such extent as shall be necessary to defray all proper expenses incurred by the board or commission in the performance of its duties but such charges shall not be fixed at a level that will raise amounts in excess of the amount estimated to be so required.

[1]*N.J.S.A. § 45:1–3.1.*

45:1–3.3. Administrative fees charged by boards; modification

The Director of the Division of Consumer Affairs may by rule establish, prescribe, or modify administrative fees charged by boards in accordance with the ''Administrative Procedure Act,'' P.L.1968, c. 410 (C.52:14B–1 et seq.). For purposes of this section, ''administrative fees'' are charges assessed to licensees, registrants or holders of certificates, as the case may be, for board functions that are not unique to a particular board but are uniform throughout all boards. Administrative fees include, but are not limited to, fees for a duplicate or replacement license, certification or registration, late renewal fee, license reinstatement fee, and the fee for processing change of address.

45:1–4. Salary of secretary

The secretary of each of the boards mentioned in section 45:1–2 [1] of this title, whether or not a member thereof, shall be entitled to receive such reasonable salary or compensation for his services as secretary as shall be fixed by such boards, which shall be paid by the boards from their receipts, unless an appropriation is made for the expenses of such boards, in which case the same shall be paid from such appropriation.

[1]*Repealed. See, now, §§45:1–2.1, 45:1–2.2.*

45:1–5, 45:1–6. Repealed by L.1979, c. 432, § 4, eff. Feb. 14, 1980

45:1–7. Professional or occupational licenses or certificates of registration; duration; expiration; exceptions; fees

Notwithstanding any of the provisions of Title 45 of the Revised Statutes or of any other law to the contrary, all professional or occupational licenses or certificates of registration, except such licenses or certificates issued to real estate brokers or salesmen pursuant to chapter 15 of Title 45, which prior to the effective date of this act were issued for periods not exceeding one year and were annually renewable, shall, on and after the effective date of this act, be issued for periods of two years and be biennially renewable, except that licenses and business permits issued to electrical contractors and certificates of registration issued to qualified journeymen electricians pursuant to chapter 5A of Title 45 shall be issued for periods of three years and be triennially renewable; provided, however, the boards or commissions in charge of the issuance or renewal of such licenses or certificates may, in order to stagger the expiration dates thereof, provide that those first issued or renewed after the effective date of this act, shall expire and become void on a date fixed by the respective boards or commissions, not sooner than six months nor later than 29 months, after the date of issue.

The fees for the respective licenses and certificates of registration issued pursuant to this act for periods of less or greater than one year shall be in amounts proportionately less or greater than the fees established by law.

45:1–7.1. Application to holders of professional or occupational licenses

a. Notwithstanding any other act or regulation to the contrary, the provisions of this section and sections 6 and 7 of P.L.1999, c. 403 (C.45:1–7.2 et al.) shall apply to every holder of a professional or occupational license or certificate of registration or certification issued or renewed by a board specified in section 2 of P.L. 1978, c. 73 (C.45:1–15), who seeks renewal of that license or certificate.

b. Every holder of a professional or occupational license or certificate of registration or certification, issued or renewed by a board specified in section 2 of P.L.1978, c. 73 (C.45:1–15), who seeks renewal shall submit a renewal application and pay a renewal fee prior to the date of expiration of the license or certificate of registration or certification. If the holder does not renew the license or certificate prior to its expiration date, the holder may renew it within 30 days of its expiration date by submitting a renewal application and paying a renewal fee and a late fee. Any professional or occupational license or certificate of registration or certification not renewed within 30 days of its expiration date shall be suspended without a hearing.

c. Any individual who continues to practice with an expired license or certificate of registration or certification after 30 days following its expiration date shall be deemed to be engaged in unlicensed practice of the regulated profession or occupation, even if no notice of suspension has been provided to the individual.

d. A professional or occupational license or certificate of registration or certification suspended pursuant to this section may be reinstated within five years following its date of expiration upon submission of a renewal application and payment of an additional reinstatement fee. An applicant seeking reinstatement of a license or certificate suspended pursuant to this section more than five years past its expiration date shall successfully complete the examination required for initial licensure, registration or certification and submit a renewal application and payment of an additional reinstatement fee.

e. A board specified in section 2 of P.L. 1978, c. 73 (C. 45:1–15) shall send a notice of renewal to each of its holders of a professional or occupational license or certificate of registration or certification, as applicable, at least 60 days prior to the expiration of the license or certificate. If the notice to renew is not sent at least 60 days prior to the expiration date, no monetary penalties or fines shall apply to the holder for failure to renew.

45:1–7.2. Reinstatement

A board may reinstate the professional or occupational license or certificate of registration or certification of an applicant whose license or certificate has been suspended pursuant to section 5 of P.L.1999, c. 403 (C.45:1–7.1), provided that the applicant otherwise qualifies for licensure, registration or certification and submits the following upon application for reinstatement:

a. Payment of all past delinquent renewal fees;

b. Payment of a reinstatement fee;

c. An affidavit of employment listing each job held during the period of suspended license, registration or certification which includes the names, addresses, and telephone numbers of each employer; and d. If applicable, satisfactory proof that the applicant has maintained proficiency by completing the continuing education hours or credits required for the renewal of an active license or certificate of registration or certification.

45:1–7.3. Renewal applications

a. Renewal applications for all professional or occupational licenses or certificates of registration or certification shall provide the applicant with the option of either active or inactive renewal. A renewal applicant electing to renew as inactive shall not engage in professional or occupational practice within the State.

b. An applicant who selects the inactive renewal option shall remain on inactive status for the entire renewal period unless, upon application to the board, the board permits the inactive applicant to return to active status provided such applicant presents satisfactory proof that he has maintained proficiency by completing the continuing education hours or credits required for the renewal of an active license, registration or certification, if applicable. The continuing education hours or credits shall be completed by the applicant within three years prior to the date of application for the return to active status, unless otherwise provided by board rule.

45:1–8. Contractors; application of § 45:1–9

The provisions of this act apply to the following classes of contractors:

a. Tree experts, certified pursuant to P.L.1940, c. 100 (C. 13:1–28 et seq.[1]);

b. Home repair contractors, licensed pursuant to P.L.1960, c. 41 (C. 17:16C–62 et seq.);

c. Electrical contractors, licensed pursuant to P.L.1962, c. 162 (C. 45:5A–1 et seq.);

d. Master plumbers, licensed pursuant to P.L.1968, c. 362 (C. 45:14C–1 et seq.);

e. Well drillers, licensed pursuant to P.L.1947, c. 377 (C. 58:4A–5 et seq.); and

f. Any class of contractors who hereafter are licensed by the State.

[1]*Renumbered C. 45:15C–1 to 45:15C–10.*

45:1–9. Indication of license or certificate number on contracts, bids and advertisements

Any contractor licensed by the State shall indicate his license or certificate number on all contracts, subcontracts, bids and all forms of advertising as a contractor.

45:1–10. Disclosure of laboratory payments on bills to patients and third party payors

It shall be unlawful for any person licensed in the State of New Jersey to practice medicine or surgery, dentistry, osteopathy, podiatry or chiropractic to agree with any clinical, bio-analytical or hospital laboratory, wheresoever located, to make payments to such laboratory for individual tests, combination of tests, or test series for patients unless such person discloses on the bills to patients and third party payors the name and address of such laboratory and the net amount or amounts paid or to be paid to such laboratory for individual tests, combination of tests or test series.

45:1–10.1. Claims for third party payment; licensed health care professional ; responsibility for filing

Effective 12 months after the adoption of regulations establishing standard health care enrollment and claim forms by the Commissioner of Banking and Insurance pursuant to section 1 of P.L.1999, c. 154 (C.17B:30–23), a health care professional licensed pursuant to Title 45 of the Revised Statutes is responsible for filing all claims for third party payment, including claims filed on behalf of the licensed professional's patient for any health care service provided by the licensed professional that is eligible for third party payment, except that at the patient's option, the patient may file the claim for third party payment.

a. In the case of a claim filed on behalf of the professional's patient, the professional shall file the claim within 60 days of the last date of service for a course of treatment, on the standard claim form adopted by the Commissioner of Banking and Insurance pursuant to section 1 of P.L.1999, c. 154 (C.17B:30–23).

b. In the case of a claim in which the patient has assigned his benefits to the professional, the professional shall file the claim within 180 days of the last date of service for a course of treatment, on the standard claim form adopted by the Commissioner of Banking and Insurance pursuant to section 1 of P.L.1999, c. 154 (C.17B:30–23). If the professional does not file the claim within 180 days of the last date of service for a course of treatment, the third party payer shall reserve the right to deny payment of the claim, in accordance with regulations established by the Commissioner of Banking and Insurance, and the professional shall be prohibited from seeking any payment directly from the patient.

(1) In establishing the standards for denial of payment, the Commissioner of Banking and Insurance shall consider the good faith use of information provided by the patient to the professional with respect to the identity of the patient's third party payer, delays in filing a claim related to coordination of benefits between third party payers and any other factors the commissioner deems appropriate, and, accordingly, shall define specific instances where the sanctions permitted pursuant to this subsection shall not apply.

(2) A professional who fails to file a claim within 180 days and whose claim for payment has been denied by the third party payer in accordance with this subsection may, in the discretion of a judge of the Superior Court, be permitted to refile the claim if the third party payer has not been substantially prejudiced thereby. Application to the court for permission to refile a claim shall be ma de within 14 days of notification of denial of payment and shall be made upon motion based upon affidavits showing sufficient reasons for the failure to file the claim with the third party payer within 180 days.

c. The provisions of this section shall not apply to any claims filed pursuant to P.L.1972, c. 70 (C.39:6A–1 et seq.).

d. A health care professional who violates the provisions of subsection a. of this section may be subject to a civil penalty of $250 for each violation plus $50 for each day after the 60th day that the provider fails to submit a claim. The penalty shall be sued for and collected by the Division of Consumer Affairs in the Department of Law and Public Safety pursuant to ''the penalty enforcement law,'' N.J.S.2A:58–1 et seq.

45:1–11. Violations; penalty

Any person violating this act shall be guilty of a misdemeanor.

45:1–12. Podiatrist, optometrist or psychologist or professional service corporation; charge for completion of claim form for health insurance; fine; collection and enforcement

No podiatrist, optometrist or psychologist and no professional service corporation engaging in the practice of podiatry, optometry or psychology in this State shall charge a patient an extra fee for services rendered in completing a medical claim form in connection with a health insurance policy. Any person violating this act shall be subject to a fine of $100.00 for each offense.

Such penalty shall be collected and enforced by summary proceedings pursuant to the Penalty Enforcement Law (N.J.S. 2A:58–1 et seq.). The Superior Court and municipal court shall have jurisdiction within its territory of such proceedings. Process shall be either in the nature of a summons or warrant and shall issue in the name of the State, upon the complaint of the State Board of Medical Examiners with respect to podiatrists, the New Jersey State Board of Optometry for optometrists or the State Board of Psychological Examiners for psychologists.

45:1–13. Repealed by L.1999, c. 403, § 12, eff. Jan. 18, 2000

45:1–14. Legislative findings and declarations; liberal construction of act

The Legislature finds and declares that effective implementation of consumer protection laws and the administration of laws pertaining to the professional and occupational boards located within the Division of Consumer Affairs require uniform investigative and enforcement powers and procedures and uniform standards for license revocation, suspension and other disciplinary proceedings by such boards. This act is deemed remedial, and the provisions hereof should be afforded a liberal construction.

45:1–15. Boards and professions or occupations regulated by or through such boards; application of act

The provisions of this act shall apply to the following boards and all professions or occupations regulated by, through or with the advice of those boards: the New Jersey State Board of Accountancy, the New Jersey State Board of Architects, the New Jersey State Board of Cosmetology and Hairstyling, the Board of Examiners of Electrical Contractors, the New Jersey State Board of Dentistry, the State Board of Mortuary Science of New Jersey, the State Board of Professional Engineers and Land

Surveyors, the State Board of Marriage and Family Therapy Examiners, the State Board of Medical Examiners, the New Jersey Board of Nursing, the New Jersey State Board of Optometrists, the State Board of Examiners of Ophthalmic Dispensers and Ophthalmic Technicians, the Board of Pharmacy, the State Board of Professional Planners, the State Board of Psychological Examiners, the State Board of Examiners of Master Plumbers, the State Board of Shorthand Reporting, the State Board of Veterinary Medical Examiners, the Acupuncture Examining Board, the State Board of Chiropractic Examiners, the State Board of Respiratory Care, the State Real Estate Appraiser Board, the State Board of Social Work Examiners, the State Board of Physical Therapy Examiners, the Professional Counselor Examiners Committee, the New Jersey Cemetery Board, the Orthotics and Prosthetics Board of Examiners, the Occupational Therapy Advisory Council, the Electrologists Advisory Committee, the Alcohol and Drug Counselor Committee, the Fire Alarm, Burglar Alarm, and Locksmith Advisory Committee, the Home Inspection Advisory Committee, the Massage, Bodywork and Somatic Therapy Examining Committee, and the Audiology and Speech–Language Pathology Advisory Committee.

45:1–15.1. Rules and regulations

Consistent with their enabling acts, P.L.1978, c. 73 (C.45:1–14 et seq.) and the ''Administrative Procedure Act,'' P.L.1968, c . 410 (C.52:14B–1 et seq.), the boards and others set forth in section 2 of P .L.1978, c. 73 (C.45:1–15) are authorized to adopt rules and regulations to serve the public health, safety and welfare.

45:1–16. Definitions

As used within this act the following words or terms shall have the indicated definition unless the context clearly indicates otherwise. ''Board'' means any professional or occupational licensing board designated in section 2 of this act.[1]

''Director'' means the Director of the Division of Consumer Affairs in the Department of Law and Public Safety.

''Person'' means any natural person or his legal representative, partnership, corporation, company, trust, business entity or association, and any agent, employee, salesman, partner, officer, director, member, stockholder, associate, trustee or cestuis que trust thereof.

[1]*N.J.S.A. § 45:1–15.*

45:1–17. Powers of Attorney General to implement act and administer law enforcement activities of boards

In implementing the provisions of this act and administering the law enforcement activities of those professional and occupational boards located within the Division of Consumer Affairs, the Attorney General may:

a. After advice to the board or boards in question of his intent toproceed under this section, and the specific action he intends to take, andthe failure of such board or boards to take steps in accordance with theadvice of the Attorney General within 30 days of receipt of such advice,promulgate rules and regulations consistent with the provisions of this actand the Administrative Procedure Act, P.L.1968, c. 410 (C. 52:14B–1 etseq.) governing the procedure for administrative hearings before all boardswithin the Division of Consumer Affairs. Such rules and regulations shall govern administrative complaints, answers thereto, issuance of subpenas, appointment of hearing examiners, adjournments, submission of proposed findings of fact and conclusions of law, the filing of briefs, and such other procedural aspects of administrative hearings before the boards as the Attorney General may deem necessary; provided, however,

nothing herein authorized shall be construed to require the Attorney General to promulgate rules regarding prehearing investigative procedures.

b. After advice to the board or boards in question of his intent to proceed under this section, and the specific action he intends to take, and the failure of such board or boards to take steps in accordance with the advice of the Attorney General within 30 days of receipt of such advice, promulgate substantive rules and regulations consistent with the provisions of any statute governing the activities of any licensing agency, board or committee located within the Division of Consumer Affairs, which shall be limited to disciplinary matters and arbitrary restrictions on initial licensure. In addition to promulgating such rules and regulations, the Attorney General may direct that any proposed or existing regulation be amended, abandoned or repealed. Prior to the final adoption of any regulation affecting the activities of any professional or occupational licensing agency, board or committee located within the division and prior to the issuance of any directive to amend, abandon or repeal any regulation, the Attorney General or his designee shall first consult with the agency, board or committee whose activities are affected regarding the proposed action.

c. After a full consideration of all relevant facts and the applicable law, may direct the initiation of any appropriate enforcement action by a professional or occupational licensing board or set aside, modify or amend, as may be necessary, any action or decision of a licensing agency, board or committee located within the Division of Consumer Affairs; provided, however, no such action shall be directed by the Attorney General in reviewing the action or decision of an agency, board or committee unless such action or decision is contrary to applicable law.

45:1–18. Investigative powers of boards, director or attorney general

Whenever it shall appear to any board, the director or the Attorney General that a person has engaged in, or is engaging in any act or practice declared unlawful by a statute or regulation administered by such board, or when the board, the director or the Attorney General shall deem it to be in the public interest to inquire whether any such violation may exist, the board or the director through the Attorney General, or the Attorney General acting independently, may exercise any of the following investigative powers:

a. Require any person to file on such form as may be prescribed, a statement or report in writing under oath, or otherwise, as to the facts and circumstances concerning the rendition of any service or conduct of any sale incidental to the discharge of any act or practice subject to an act or regulation administered by the board;

b. Examine under oath any person in connection with any act or practice subject to an act or regulation administered by the board;

c. Inspect any premises from which a practice or activity subject to an act or regulation administered by the board is conducted;

d. Examine any goods, ware or item used in the rendition of a practice or activity subject to an act or regulation administered by the board;

e. Examine any record, book, document, account or paper prepared or maintained by or for any professional or occupational licensee in the regular course of practicing such profession or engaging in such occupation or any individual engaging in practices subject to an act or regulation administered by the board. Nothing in this subsection shall require the notification or consent of the person to whom the record, book, account or paper pertains, unless otherwise required by law;

f. For the purpose of preserving evidence of an unlawful act or practice, pursuant to an order of the Superior Court, impound any record, book, document, account, paper, goods, ware, or item used, prepared or maintained by or for any board licensee in the regular course of practicing such profession or engaging in such occupation or any individual engaging in a practice or activity subject to an act or regulation administered by the board. In such cases as may be necessary, the Superior Court may, on application of the Attorney General, issue an order sealing items or material subject to this subsection; and

g. Require any board licensee, permit holder or registered or certified person to submit to an assessment of skills to determine whether the board licensee, permit holder or registered or certified person can continue to practice with reasonable skill and safety.

In order to accomplish the objectives of this act or any act or regulation administered by a board, the Attorney General may hold such investigative hearings as may be necessary and the board, director or Attorney General may issue subpoenas to compel the attendance of any person or the production of books, records or papers at any such hearing or inquiry.

45:1–19. Failure or refusal to file statement or report, refusal of access to premises or failure to obey subpena; penalty

If any person shall fail or refuse to file any statement or report or refuse access to premises from which a licensed profession or occupation is conducted in any lawfully conducted investigative matter or fail to obey a subpena issued pursuant to this act, the Attorney General may apply to the Superior Court and obtain an order:

a. Adjudging such person in contempt of court; or

b. Granting such other relief as may be required; or

c. Suspending the license of any such person unless and until compliance with the subpena or investigative demand is effected.

45:1–20. Compelling testimony or production of book, paper or document; immunity from prosecution

If any person shall refuse to testify or produce any book, paper, or other document in any proceeding under this act for the reason that the testimony or evidence, documentary or otherwise, required of him may tend to incriminate him, convict him of a crime, or subject him to a penalty or forfeiture, and shall, notwithstanding, be directed to testify or to produce such book, paper, or document by the Attorney General, he shall comply with such direction.

A person who is entitled by law to, and does assert such privilege, and who complies with such direction of the Attorney General shall not thereafter be prosecuted or subjected to any penalty or forfeiture in any criminal proceeding which arises out of and relates to the subject matter of the proceeding. No person so testifying shall be exempt from prosecution or punishment for perjury or false swearing committed by him in giving such testimony or from any civil or administrative action arising from such testimony.

45:1–21. Grounds for refusal to admit to examination or denial, suspension or revocation of any certificate, registration or license; definitions

A board may refuse to admit a person to an examination or may refuse to issue or may suspend or revoke any certificate, registration or license issued by the board upon proof that the applicant or holder of such certificate, registration or license:

a. Has obtained a certificate, registration, license or authorization to sit for an examination, as the case may be, through fraud, deception, or, misrepresentation;

b. Has engaged in the use or employment of dishonesty, fraud, deception, misrepresentation, false promise or false pretense;

c. Has engaged in gross negligence, gross malpractice or gross incompetence which damaged or endangered the life, health, welfare, safety or property of any person;

d. Has engaged in repeated acts of negligence, malpractice or incompetence;

e. Has engaged in professional or occupational misconduct as may be determined by the board;

f. Has been convicted of, or engaged in acts constituting, any crime or offense involving moral turpitude or relating adversely to the activity regulated by the board. For the purpose of this subsection a judgment of conviction or a plea of guilty, non vult, nolo contendere or any other such disposition of alleged criminal activity shall be deemed a conviction;

g. Has had his authority to engage in the activity regulated by the board revoked or suspended by any other state, agency or authority for reasons consistent with this section;

h. Has violated or failed to comply with the provisions of any act or regulation administered by the board;

i. Is incapable, for medical or any other good cause, of discharging the functions of a licensee in a manner consistent with the public's health, safety and welfare;

j. Has repeatedly failed to submit completed applications, or parts of, or documentation submitted in conjunction with, such applications, required to be filed with the Department of Environmental Protection;

k. Has violated any provision of P.L.1983, c. 320 (C.17:33A–1 et seq.) or any insurance fraud prevention law or act of another jurisdiction or has been adjudicated, in civil or administrative proceedings, of a violation of P.L.1983, c. 320 (C.17:33A–1 et seq.) or has been subject to a final order, entered in civil or administrative proceedings, that imposed civil penalties under that act against the applicant or holder;

l. Is presently engaged in drug or alcohol use that is likely to impair the ability to practice the profession or occupation with reasonable skill and safety. For purposes of this subsection, the term ''presently'' means at this time or any time within the previous 365 days;

m. Has prescribed or dispensed controlled dangerous substances indiscriminately or without good cause, or where the applicant or holder knew or should have known that the substances were to be used for unauthorized consumption or distribution;

n. Has permitted an unlicensed person or entity to perform an act for which a license or certificate of registration or certification is required by the board, or aided and abetted an unlicensed person or entity in performing such an act;

o. Advertised fraudulently in any manner.

The division is authorized, for purposes of facilitating determinations concerning licensure eligibility, to require the fingerprinting of each applicant in accordance with applicable State and federal laws, rules and regulations. Each applicant shall submit the applicant's name, address, and written consent to the director for a criminal history record background check to be performed. The

division is authorized to receive criminal history record information from the State Bureau of Identification in the Division of State Police and the Federal Bureau of Investigation. Upon receipt of such notification, the division shall forward the information to the appropriate board which shall make a determination regarding the issuance of licensure. The applicant shall bear the cost for the criminal history record background check, including all costs of administering and processing the check, unless otherwise provided for by an individual enabling act. The Division of State Police shall promptly notify the division in the event an applicant or licensee, who was the subject of a criminal history record background check pursuant to this section, is convicted of a crime or offense in this State after the date the background check was performed.

For purposes of this act:

''Completed application'' means the submission of all of the information designated on the checklist, adopted pursuant to section 1 of P.L.1991, c. 421 (C.13:1D–101), for the class or category of permit for which application is made.

''Permit'' has the same meaning as defined in section 1 of P.L.1991, c. 421 (C.13:1D–101).

45:1–21.1. Annual summary of compliance information and attendance at continuing education seminars; costs; information deemed public records

a. A board obtaining information from the Department of Environmental Protection pursuant to section 1 of P.L.1991, c. 418 (C. 13:1D–110) on the compliance of a member of a regulated profession with the requirements for completed applications of the department, shall annually develop a detailed written summary of the information gathered by the department pursuant to P.L.1991, c. 418 (C. 13:1D–110) regarding compliance with the department's requirements for completed applications and attendance records for continuing education seminars required to be filed with the department pursuant to section 2 of P.L.1991, c. 419 (C. 13:1D–117).

b. Any reasonable costs incurred in preparation of the report required pursuant to this section may be included in the charges authorized pursuant to P.L.1974, c. 46 (C. 45:1–3.2).

c. Information required to be compiled by a board pursuant to this section, shall be deemed to be public records subject to the requirements of

45:1–21.2. Suspension of certain licenses; hearing

The director or a board shall suspend, as appropriate, after a hearing, the license, registration or certification of any person who has been certified by a lender or guarantor and reported to the director or the board, as the case may be, for nonpayment or default of a State or federal direct or guaranteed educational loan. The license, registration or certification shall not be reissued until the person provides the director or board with a written release issued by the lender or guarantor stating that the person has cured the default or is making payments on the loan in accordance with a repayment agreement approved by the lender or guarantor. If the person has continued to meet all other requirements for licensure, registration or certification during the suspension, reinstatement shall be automatic upon receipt of the notice and payment of any reinstatement fee the director or the board may impose.

45:1–21.3. Licensed health care professionals; penalties for violation of § 30:6D–5.3

A health care professional licensed or otherwise authorized to practice as a health care professional pursuant to Title 45 of the Revised Statutes who violates the provisions of section 3 of P.L.2003, c. 191 (C.30: 6D–5.3) shall, in addition to being liable to a civil penalty pursuant to section 4 of P.L.2003, c. 191 (C.30:6D–5.4), be subject to revocation of that individual's professional license or

other authorization to practice as a health care professional by the appropriate licensing board in the Division of Consumer Affairs in the Department of Law and Public Safety, after appropriate notice and opportunity for a hearing.

45:1–22. Additional or alternative penalties to revocation, suspension or refusal to renew; temporary order suspending or limiting license; subpoena

In addition or as an alternative, as the case may be, to revoking, suspending or refusing to renew any license, registration or certificate issued by it, a board may, after affording an opportunity to be heard:

a. Issue a letter of warning, reprimand, or censure with regard to any act, conduct or practice which in the judgment of the board upon consideration of all relevant facts and circumstances does not warrant the initiation of formal action;

b. Assess civil penalties in accordance with this act;

c. Order that any person violating any provision of an act or regulation administered by such board to cease and desist from future violations thereof or to take such affirmative corrective action as may be necessary with regard to any act or practice found unlawful by the board;

d. Order any person found to have violated any provision of an act or regulation administered by such board to restore to any person aggrieved by an unlawful act or practice, any moneys or property, real or personal, acquired by means of such act or practice; provided, however, no board shall order restoration in a dollar amount greater than those moneys received by a licensee or his agent or any other person violating the act or regulation administered by the board;

e. Order any person, as a condition for continued, reinstated or renewed licensure, to secure medical or such other professional treatment as may be necessary to properly discharge licensee functions;

f. Order any person, as a condition for continued, reinstated or renewed licensure, to submit to any medical or diagnostic testing and monitoring or psychological evaluation which may be required to evaluate whether continued practice may jeopardize the safety and welfare of the public;

g. Order any person, as a condition for continued, reinstated or renewed licensure, to submit to an assessment of skills to determine whether the licensee can continue to practice with reasonable skill and safety, and to take and successfully complete educational training determined by the board to be necessary;

h. Order any person, as a condition for continued, reinstated or renewed licensure, to submit to an assessment of skills to determine whether the licensee can continue to practice with reasonable skill and safety, and to submit to any supervision, monitoring or limitation on practice determined by the board to be necessary.

A board may, upon a duly verified application of the Attorney General that either provides proof of a conviction of a court of competent jurisdiction for a crime or offense involving moral turpitude or relating adversely to the regulated profession or occupation, or alleges an act or practice violating any provision of an act or regulation administered by such board, enter a temporary order suspending or limiting any license issued by the board pending plenary hearing on an administrative complaint; provided, however, no such temporary order shall be entered unless the application made to the board

palpably demonstrates a clear and imminent danger to the public health, safety and welfare and notice of such application is given to the licensee affected by such order. If, upon review of the Attorney General's application, the board determines that, although no palpable demonstration of a clear and imminent danger has been made, the licensee's continued unrestricted practice pending plenary hearing may pose a risk to the public health, safety and welfare, the board may order the licensee to submit to medical or diagnostic testing and monitoring, or psychological evaluation, or an assessment of skills to determine whether the licensee can continue to practice with reasonable skill and safety.

In any administrative proceeding commenced on a complaint alleging a violation of an act or regulation administered by a board, such board may issue subpoenas to compel the attendance of witnesses or the production of books, records, or documents at the hearing on the complaint.

45:1–23. Summary proceeding in Superior Court; injunction; orders necessary to prevent unlawful practice or remedy past unlawful activity

Whenever it shall appear to a board, the director or the Attorney General that a violation of any act, including the unlicensed practice of the regulated profession or occupation, or regulation administered by such board has occurred, is occurring, or will occur, the Attorney General, in addition to any other proceeding authorized by law, may seek and obtain in a summary proceeding in the Superior Court an injunction prohibiting such act or practice. In any such proceeding the court may assess a civil penalty in accordance with the provisions of this act, order restoration to any person in interest of any moneys or property, real or personal, acquired by means of an unlawful act or practice and may enter such orders as may be necessary to prevent the performance of an unlawful practice in the future and to fully remedy any past unlawful activity. In any action brought pursuant to this section, the court shall not suspend or revoke any license issued by a board.

45:1–24. Failure to comply with order of board directing payment of penalties or restoration of moneys or property; enforcement

Upon the failure of any person to comply within 10 days after service of any order of a board directing payment of penalties or restoration of moneys or property, the Attorney General or the secretary of such board may issue a certificate to the Clerk of the Superior Court that such person is indebted to the State for the payment of such penalty and the moneys or property ordered restored. A copy of such certificate shall be served upon the person against whom the order was entered. Thereupon the clerk shall immediately enter upon his record of docketed judgments the name of the person so indebted and of the State, a designation of the statute under which the penalty is imposed, the amount of the penalty imposed, and amount of moneys ordered restored, a listing of property ordered restored, and the date of the certification. Such entry shall have the same force and effect as the entry of a docketed judgment in the Superior Court, and the Attorney General shall have all rights and remedies of a judgment creditor in addition to exercising any other available remedies. Such entry, however, shall be without prejudice to the right of appeal to the Appellate Division of the Superior Court from the board's order.

An action to enforce the provisions of any order entered by a board or to collect any penalty levied thereby may be brought in any municipal court or the Superior Court in summary manner pursuant to the Penalty Enforcement Act, (N.J.S. 2A:58–1 et seq.) and the rules of court governing the collection of civil penalties. Process in such action shall be by summons or warrant, and in the event that the defendant fails to answer such action, the court shall issue a warrant for the defendant's arrest for the purpose of bringing such person before the court to satisfy any order entered.

45:1–25. Violations; civil penalty; action to collect or enforce

a. Any person who engages in any conduct in violation of any provision of an act or regulation administered by a board shall, in addition to any other sanctions provided herein, be liable to a civil penalty of not more than $10,000 for the first violation and not more than $20,000 for the second and each subsequent violation. For the purpose of construing this section, each act in violation of any provision of an act or regulation administered by a board shall constitute a separate violation and shall be deemed a second or subsequent violation under the following circumstances:

(1) an administrative or court order has been entered in a prior, separate and independent proceeding;

(2) the person is found within a single proceeding to have committed more than one violation of any provision of an act or regulation administered by a board; or

(3) the person is found within a single proceeding to have committed separate violations of any provision of more than one act or regulation administered by a board.

b. In lieu of an administrative proceeding or an action in the Superior Court, the Attorney General may bring an action in the name of any board for the collection or enforcement of civil penalties for the violation of any provision of an act or regulation administered by such board. Such action may be brought in summary manner pursuant to the "Penalty Enforcement Law of 1999," P.L.1999, c. 274 (C.2A:58–10 et seq.) and the rules of court governing actions for the collection of civil penalties in the municipal court where the offense occurred. Process in such action may be by summons or warrant and in the event that the defendant in such action fails to answer such action, the court shall, upon finding an unlawful act or practice to have been committed by the defendant, issue a warrant for the defendant's arrest in order to bring such person before the court to satisfy the civil penalties imposed. In any action commenced pursuant to this section, the court may order restored to any person in interest any moneys or property acquired by means of an unlawful act or practice.

c. Any action alleging the unlicensed practice of a profession or occupation shall be brought pursuant to this section or, where injunctive relief is sought, by an action commenced in the Superior Court.

d. In any action brought pursuant to this act, a board or the court may order the payment of costs for the use of the State, including, but not limited to, costs of investigation, expert witness fees and costs, attorney fees and costs, and transcript costs.

45:1–26. Repeal of inconsistent acts and parts of acts

All acts and parts of acts inconsistent with this act are hereby superseded and repealed.

45:1–27. Severability

If any provision of this law or the application thereof to any person or circumstance is held invalid, the invalidity shall not affect other provisions or applications of the law which can be given effect without the invalid provision or application, and to this end the provisions of this law are severable.

CHAPTER 14. PHARMACY

45:14–1 to 45:14–4. Repealed by L.2003, c. 280, § 42

45:14–5. Repealed by L.1979, c. 432, § 3, eff. Feb. 14, 1980

45:14–6 to 45:14–11.1. Repealed by L.2003, c. 280, § 42

45:14–11.2 to 45:14–11.10. Repealed by L.1995, c. 79, § 7, eff. July 10,1995

45:14–11.11 to 45:14–12.1. Repealed by L.2003, c. 280, § 42

45:14–12.2. Repealed by L.1999, c. 403, § 12, eff. Jan. 18, 2000

45:14–13 to 45:14–26.2. Repealed by L.2003, c. 280, § 42

45:14–26.3. Repealed by L.1979, c. 432, § 1, eff. Feb. 14, 1980

45:14–27. Repealed by L.2003, c. 280, § 42

45:14–28. Repealed by L.1979, c. 432, § 6, eff. Feb. 14, 1980

45:14–29 to 45:14–34. Repealed by L.2003, c. 280, § 42

45:14–35. Repealed by L.1999, c. 403, § 12, eff. Jan. 18, 2000

45:14–36 to 45:14–36.4. Repealed by L.2003, c. 280,§ 42

45:14–37 to 45:14–39. Repealed by L.1979, c. 432, § 1, eff. Feb. 14, 1980

45:14–40. Short title

a. This act shall be known and may be cited as the ‘‘New Jersey Pharmacy Practice Act.’’

b. The practice of pharmacy in this State is declared a health care professional practice affecting the public health, safety and welfare and is subject to regulation and control in the public interest. It is further declared to be a matter of public interest and concern that the practice of pharmacy merits and receives the confidence of the public and that only qualified persons be permitted to engage in the practice of pharmacy in this State. This act shall be liberally construed to carry out these objectives and purposes.

c. It is the purpose of this act to promote, preserve and protect the public health, safety and welfare by and through the effective control and regulation of the practice of pharmacy, the licensure of pharmacists and the permitting, control and regulation of all pharmacy practice sites in this State that engage in the practice of pharmacy.

45:14–41. Definitions

As used in this act:

‘‘Administer’’ means the direct application of a drug to the body of a patient or research subject by subcutaneous, intramuscular or intradermal injection, inhalation or ingestion by a pharmacist engaged in collaborative practice or in accordance with regulations jointly promulgated by the boardand the State Board of Medical Examiners.

‘‘Automated medication device’’ means a discrete unit that performs specific drug dispensing operations.

‘‘Automated medication system’’ means any process that performs operations or activities, other than compounding or administration, relative to the storage, packaging, dispensing and distribution of medications and which collects, controls and maintains all transaction information.

''Board of Pharmacy'' or ''board'' means the New Jersey State Board of Pharmacy.

''Certification'' means a certification awarded by a recognized nongovernment specialty organization to signify that a pharmacist has met predetermined qualifications and to signify to the public that the pharmacist is competent to practice in the designated specialty.

''Collaborative drug therapy management'' means a written protocol directed on a voluntary basis by a patient's physician, with the patient's consent, that is between a patient's physician who is treating the patient for a specific disease and a pharmacist for cooperative management of a patient's drug, biological and device-related health care needs, which shall be conducted in accordance with regulations jointly promulgated by the board and the State Board of Medical Examiners and shall only include the collecting, analyzing and monitoring of patient data; ordering or performing of laboratory tests based on the standing orders of a physician as set forth in the written protocol; ordering of clinical tests based on the standing orders of a physician as set forth in the written protocol, provided those laboratory tests are granted waived status in accordance with the provisions of the ''New Jersey Clinical Laboratory Improvement Act,'' P.L.1975, c. 166 (C.45:9–42.26 et seq.) and are for the treatment of a disease state identified jointly by the board and the State Board of Medical Examiners as subject to collaborative drug therapy management; modifying, continuing or discontinuing drug or device therapy; and therapeutic drug monitoring with appropriate modification to dose, dosage regimen, dosage forms or route of administration. The interpretation of clinical or laboratory tests under a written protocol may only be performed by a pharmacist in direct consultation with a physician .

''Compounding'' means the preparation, mixing, assembling, packaging or labeling of a drug or device as the result of a practitioner's prescription or initiative based on the relationship of the practitioner or patient with the pharmacist in the course of professional practice or for the purpose of, or incident to, research, teaching or chemical analysis and not for sale or dispensing. Compounding also includes the preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns. Nothing in this act is meant to limit a prescriber's ability under pre-existing law to order a compounded medication for use in the prescriber's practice, as permitted by State and federal law.

''Confidential information'' means information that is identifiable as to the patient involved that a pharmacist accesses, transmits or maintains in a patient's record or which is communicated to or by the patient as part of patient counseling.

''Credentialing'' means the process by which an approved academic institution awards a certificate to signify that the credentialed pharmacist has completed the required courses, examinations or both, that indicate advanced knowledge of a particular area of pharmacy.

''Deliver'' or ''delivery'' means the actual, constructive or attempted transfer of a drug or device from one person to another, whether or not for consideration.

''Device'' means an instrument, apparatus, implement, machine, contrivance, implant or other similar or related article, including any component part or accessory, which is required under federal law to bear the label ''RX Only.''

''Dispense'' or ''dispensing'' means the procedure entailing the interpretation of a practitioner's prescription order for a drug, biological or device, and pursuant to that order the proper selection, measuring, compounding, labeling and packaging in a proper container for subsequent administration to, or use by, a patient.

''Dosage form'' means the physical formulation or medium in which the product is intended, manufactured and made available for use, including, but not limited to: tablets, capsules, oral solutions, aerosols, inhalers, gels, lotions, creams, ointments, transdermals and suppositories, and the particular form of the above which utilizes a specific technology or mechanism to control, enhance or direct the release, targeting, systemic absorption or other delivery of a dosage regimen in the body.

''Drug or medication'' means articles recognized as drugs in any official compendium, or supplement thereto, designated from time to time by the board for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or other animals; articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or other animals; articles intended to affect the structure or any function of the body of humans or other animals, except that a food, dietary ingredient or dietary supplement, as those terms are defined in 21 U.S.C.s.321, is not a drug solely because the label or the labeling contains such a claim; and articles intended for use as a component of and articles specified in this definition of ''drug or medication.''

''Drug utilization review'' includes, but is not limited to, the following activities:

(1) Evaluation of prescription drug orders and patient records for known allergies, rational therapy-contraindications, appropriate dose and route of administration and appropriate directions for use;

(2) Evaluation of prescription drug orders and patient records for duplication of therapy;

(3) Evaluation of prescription drug orders and patient records for interactions between drug-drug, drug-food, drug-disease and adverse drug reactions; and

(4) Evaluation of prescription drug orders and patient records for proper utilization, including over-or under-utilization, and optimum therapeutic outcomes.

''Extern'' means any person who is in the fifth or sixth year of college or the third or fourth professional year, at an accredited school or college of pharmacy approved by the board, who is assigned to a training site for the purpose of acquiring accredited practical experience under the supervision of the school or college at which the person is enrolled.

''Electronic means'' means any electronic or digital transmission format, including facsimile or computer generated messaging.

''Immediate supervision'' means a level of control which assures that the pharmacist is physically present at the pharmacy practice site and has the responsibility for accuracy and safety with respect to the actions of pharmacy technicians, interns and externs.

''Intern'' means any person who has graduated from an accredited school or college of pharmacy approved by the board, or if a foreign pharmacy graduate, any person who has met all of the requirements of the board, and who is being trained by an approved preceptor for the purpose of acquiring accredited practical experience and who has first registered for that purpose with the board.

''Labeling'' means the process of preparing and affixing a label to any drug container, exclusive however, of the labeling by a manufacturer, packer or distributor of a non-prescription drug or commercially packaged legend drug or device.

''Licensure'' means the process by which the board grants permission to an individual to engage in the practice of pharmacy upon finding that the applicant has attained the degree of competency necessary to ensure that the public health, safety and welfare will be protected.

''Medication error'' means a preventable event that may cause or lead to inappropriate use of a medication or patient harm while the medication is in the control of the practitioner, patient or consumer.

''Medication order'' means a prescription for a specific patient in an institutional setting.

''Modifying'' means to change a specific drug, the dosage, or route of delivery of a drug currently being administered for an existing diagnosis pursuant to a collaborative drug therapy management.

''Non-prescription drug or device'' means a drug or device which may be obtained without a prescription and which is labeled for consumer use in accordance with the requirements of the laws and rules of this State and the federal government.

''Permit'' means the authorization granted by the board to a site to engage in the practice of pharmacy.

''Person'' means an individual, corporation, partnership, association or any other legal entity including government.

''Pharmaceutical care'' means the provision by a pharmacist of drug therapy review and other related patient care services intended to achieve positive outcomes related to the treatment, cure or prevention of a disease; control, elimination or reduction of a patient's symptoms; or arresting or slowing of a disease process as defined by the rules and regulations of the board.

''Pharmacist'' means an individual currently licensed by this State to engage in the practice of pharmacy.

''Pharmacist-in-charge'' means a pharmacist who accepts responsibility for the operation of a pharmacy practice site in conformance with all laws and rules pertinent to the practice of pharmacy and the distribution of drugs.

''Pharmacist in collaborative practice'' means a pharmacist engaged in the collaborative drug therapy management of a patient's drug, biological and device-related health care needs pursuant to a written protocol, in collaboration with a licensed physician and in accordance with the regulations jointly promulgated by the board and the State Board of Medical Examiners.

''Pharmacy practice site'' means any place in this State where drugs are dispensed or pharmaceutical care is provided by a licensed pharmacist, but shall not include a medical office under the control of a licensed physician.

''Pharmacy technician'' means an individual working in a pharmacy practice site who, under the immediate supervision of a pharmacist, assists in pharmacy activities as permitted by section 41 of this act and the rules and regulations of the board that do not require the professional judgment of a pharmacist.

''Practice of pharmacy'' means a health care service by a pharmacist that includes: compounding, dispensing and labeling of drugs, biologicals, radio pharmaceuticals or devices; overseeing automated medication systems; interpreting and evaluating prescriptions; administering and distributing drugs, biologicals and devices; maintaining prescription drug records; advising and consulting on the therapeutic values, content, hazards and uses of drugs, biologicals and devices; managing and monitoring drug therapy; collecting, analyzing and monitoring patient data; performing drug utilization reviews; storing prescription drugs and devices; supervising technicians, interns and externs; and such other acts, services, operations or transactions necessary, or incidental to, providing pharmaceutical care and education. In accordance with written guidelines or protocols established with a licensed physician, the

‘‘practice of pharmacy’’ also includes collaborative drug therapy management including modifying, continuing or discontinuing drug or device therapy; ordering or performing of laboratory tests under collaborative drug therapy management; and ordering clinical tests, excluding laboratory tests, unless those tests are part of collaborative drug therapy management.

‘‘Practitioner’’ means an individual currently licensed, registered or otherwise authorized by the jurisdiction in which the individual practices to administer or prescribe drugs in the course of professional practice.

‘‘Preceptor’’ means an individual who is a pharmacist, meets the qualifications under the rules and regulations of the board, and participates in the instructional training of pharmacy interns and externs.

‘‘Prescription’’ means a lawful order of a practitioner for a drug, a device or diagnostic agent for a specific patient.

‘‘Prescription drug’’ or ‘‘legend drug’’ means a drug which, under federal law, is required to be labeled prior to being delivered to the pharmacist, with either of the following statements: ‘‘Rx Only’’ or ‘‘Caution: Federal law restricts this drug to use by, or on the order of, a licensed veterinarian’’ or is required by any applicable federal or state law, rule or regulation to be dispensed pursuant to a prescription drug order or is restricted to use by a practitioner only.

‘‘Registration’’ means the process of making a list or being enrolled in an existing list.

‘‘Therapeutic interchange’’ means the substitution and dispensing of a drug chemically dissimilar from the prescription drug originally prescribed.

45:14–42. Authority of board

The board shall enforce the provisions of this act. The board shall have all of the duties, powers and authority specifically granted by or necessary for the enforcement of this act, as well as such other duties, powers and authority as it may be granted from time to time by applicable law.

45:14–43. Board membership

a. The board shall consist of eleven members, two of whom shall be public members and one of whom shall be a state executive department member appointed pursuant to the provisions of P.L.1971, c. 60 (C.45:1–2.1 et seq.). Each of the remaining eight members shall be pharmacists. Each pharmacist member shall have at least five years of experience in the practice of pharmacy in this State after licensure, and shall at the time of appointment and throughout their tenure: be currently licensed and in good standing to engage in the practice of pharmacy in this State, and be actively engaged in the practice of pharmacy in this State.

b. The Governor shall appoint the members of the board. Every state professional pharmacy association may send to the Governor the names of pharmacists having the qualifications required by this section, whom the Governor may appoint to fill any vacancy occurring in the board. In appointing members to the board to fill vacancies of members who engage in the practice of pharmacy, the Governor shall appoint members so that the membership of the board includes, at all times, at least one pharmacist employed by a chain drug retailer who owns or operates seven or more pharmacy practice sites, one pharmacist who is employed by a health care system and one pharmacist who owns a pharmacy practice site in this State.

c. Except for the members first appointed, members of the board shall be appointed for a term of five years, except that members of the board who are appointed to fill vacancies which occur

prior to the expiration of a former member's full term shall serve the unexpired portion of that term. The terms of the members of the board shall be staggered, so that the terms of no more than three members shall expire in any year. Each member shall serve until a successor is appointed and qualified. The present members of the board appointed pursuant to R.S.45:14–1 et seq. shall serve the balance of their terms. Any present board member appointed initially for a term of less than five years shall be eligible to serve for two additional full terms. No member of the board shall serve more than two consecutive full terms. The completion of the unexpired portion of a full term shall not constitute a full term for purposes of this subsection.

d. The Governor may remove a member of the board after a hearing for misconduct, incompetency, neglect of duty or for any other sufficient cause.

45:14–44. Annual election

a. The board shall annually elect from among its members a president and vice-president.

b. The position of executive director shall be held by a pharmacist licensed in the State of New Jersey. The executive director shall be responsible for the performance of the administrative functions of the board and those other duties that the board may direct.

45:14–45. Compensation

Each member of the board shall receive compensation pursuant to section 2 of P.L. 1977, c. 285 (C. 45:1–2.5) of $150 per day for each day on which the member is engaged in performance of the official duties of the board, and shall be reimbursed for all reasonable and necessary expenses incurred in connection with the discharge of those official duties.

45:14–46. Meetings

The board shall meet at least once every month to transact its business. The board shall meet at those additional times that it may determine. Additional meetings may be called by the president of the board or by twothirds of the members of the board.

45:14–47. Rules and regulations

The board shall make, adopt, amend and repeal those rules and regulations necessary for the proper administration and enforcement of this act. Those rules and regulations shall be promulgated in accordance with the ''Administrative Procedure Act,'' P.L.1968, c. 410 (C.52:14B–1 et seq.). Rules pertaining to collaborative drug therapy management and administration of drugs by pharmacists shall be jointly promulgated by the board and the State Board of Medical Examiners.

45:14–48. Duties of board

a. The board shall be responsible for the control and regulation of the practice of pharmacy in this State including, but not limited to, the following:

(1) The licensing by examination or by license transfer of applicants who are qualified to engage in the practice of pharmacy under the provisions of this act;

(2) The renewal of licenses to engage in the practice of pharmacy;

(3) The establishment and enforcement of professional standards and rules of conduct of pharmacists engaged in the practice of pharmacy;

(4) The establishment of requirements for pharmacists to engage in collaborative practice;

(5) The establishment of requirements jointly promulgated with the State Board of Medial Examiners for pharmacists to administer drugs directly to patients;

(6) The enforcement of those provisions of this act relating to the conduct or competence of pharmacists practicing in this State, and the suspension, revocation, failure to renew or restriction of licenses to engage in the practice of pharmacy pursuant to the provisions of P.L.1978, c. 73 (C.45:1–14 et seq.);

(7) The regulation of pharmacy practiced through any technological means;

(8) The regulation and control of automated medication systems and automated medication devices within or outside of pharmacy practice sites;

(9) The right to seize any drugs and devices found by the board to constitute an imminent danger to the public health and welfare;

(10) The establishment of minimum specifications for record keeping, prescription and patient profile record maintenance, pharmacy practice sites including, but not limited to, the physical premises, technical equipment, environment, supplies, personnel and procedures for the storage, compounding and dispensing of drugs or devices, and for the monitoring of drug therapy;

(11) The inspection of any pharmacy practice site at all reasonable hours for the purpose of determining if any provisions of the laws governing the legal distribution of drugs or devices or the practice of pharmacy are being violated. The board, its officers, inspectors and representatives shall cooperate with all agencies charged with the enforcement of the laws of the United States, of this State, and of all other states relating to drugs, devices and the practice of pharmacy;

(12) The inspection of prescription files and the prescription records of a pharmacy and the removal from the files and taking possession of any original prescription, providing that the authorized agent removing or taking possession of an original prescription shall place in the file from which it was removed a copy certified by that person to be a true copy of the original prescription removed; provided further, that the original copy shall be returned by the board to the file from which it was removed after it has served the purpose for which it was removed;

(13) The establishment of requirements for patient counseling, patient profiles and drug utilization reviews;

(14) The establishment of regulations to protect the health and safety of pharmacy patients; and

(15) The prescribing or changing of the fees for examinations, certifications, licensures, renewals and other services performed pursuant to P.L. 1974, c. 46 (C.45:1–3.1et seq.) and this act.

b. The board shall have those other duties, powers and authority as may be necessary to the enforcement of this act and to the enforcement of rules and regulations of the board, which may include, but not be limited to, the following:

(1) The determination and issuance of standards, recognition and approval of degree programs of schools and colleges of pharmacy whose graduates shall be eligible for licensure in this State, and the specifications and enforcement of requirements for practical training, including internships;

(2) The registration of externs, interns, pharmacy preceptors and pharmacy technicians;

(3) The regulation of the training, qualifications and conduct of applicants, externs, interns, pharmacy preceptors and pharmacy technicians;

(4) The collection of professional demographic data;

(5) The joining with those professional organizations and associations organized to promote the improvement of the standards of the practice of pharmacy for the protection of the health and welfare of the public or whose activities assist and facilitate the work of the board;

(6) The establishment of a bill of rights for patients concerning the health care services a patient may expect in regard to pharmaceutical care;

(7) The engagement in activities to educate consumers, to assist them in obtaining information necessary to make decisions about medication issues;

(8) The establishment of standards for the continuing education of registered pharmacists;

(9) The establishment of rules and regulations for extraordinary emergency situations that interfere with the ability to practice under the current rules and regulations;

(10) The establishment of guidelines for board approved pilot programs. The guidelines shall be complied with to implement a program that may not be presently acknowledged in this act or its rules or regulations; and

(11) The assurance that any credentialing or certification of a pharmacist is not misleading to the public.

c. (1) The board may place under seal all drugs, biologicals, radio pharmaceuticals or devices that are owned by or in the possession, custody or control of a licensee or permit holder at the time his license or permit is suspended or revoked or at the time the board refused to renew his license. Except as otherwise provided in this section, drugs, biologicals, radio pharmaceuticals or devices that are sealed pursuant to this paragraph shall not be disposed of until appeal rights under the ''Administrative Procedure Act,'' P.L.1968, c. 410 (C.52:14B–1 et seq.) have expired, or an appeal filed pursuant to that act has been determined. The court, involved in an appeal filed pursuant to the ''Administrative Procedure Act,'' may order the board, during the pendency of the appeal, to sell sealed drugs, biologicals and radio pharmaceuticals that are perishable. The proceeds of a sale shall be deposited with the court.

(2) Notwithstanding any provisions of this act to the contrary, whenever a duly authorized representative of the board finds, or has probable cause to believe, that any drug or device is outdated, adulterated or misbranded within the meaning of the ''Federal Food, Drug, and Cosmetic Act,'' 21 U.S.C.s.301 et seq., the representative shall affix to that drug or device a tag or other appropriate marking giving notice that the article is or is suspected of being outdated, adulterated or misbranded, had been detained or embargoed, and warning all persons not to remove or dispose of the article by sale or otherwise until provision for removing or disposal is given by the board, its agent or the court. No person shall remove or dispose of an embargoed drug or device by sale or otherwise without the permission of the board or its agent or, after summary proceedings have been instituted, without permission of the court.

(3) When a drug or device detained or embargoed under paragraph (2) of this subsection c. has been declared by the representative to be outdated, adulterated or misbranded, the board shall, as soon as practical thereafter, petition the judge of the court in which jurisdiction the article is detained or embargoed for an order for condemnation of that article. If the judge determines that this drug or device so detained or embargoed is not adulterated, outdated or misbranded, the board shall direct the immediate removal of the tag or other marking.

(4) If the court finds that a detained or embargoed drug or device is adulterated, outdated or misbranded, that drug or device, after entry of the decree, shall be destroyed at the expense of the owner under the supervision of a board representative and all court costs and fees, storage and other proper expenses shall be borne by the owner of that drug or device. When the outdating, adulteration or misbranding can be corrected by proper labeling or processing of the drug or device, the court, after entry of the decree and after the costs, fees and expenses have been paid and a good and sufficient bond has been posted, may direct that the drug or device be delivered to the owner thereof for labeling or processing under the supervision of a board representative. Expense of that supervision shall be paid by the owner. The bond shall be returned to the owner of the drug or device on representation to the court by the board that the drug or device is no longer in violation of the embargo and the expense of supervision has been paid.

d. Except as otherwise provided to the contrary, the board shall exercise all of its duties, powers and authority in accordance with the ''Administrative Procedure Act,'' P.L.1968, c. 410 (C.52:14B–1 et seq.).

45:14–49. Application of act

a. Except as otherwise provided in this act, it shall be unlawful for any individual to engage in the practice of pharmacy unless currently licensed to practice under the provisions of this act.

b. The provisions of this act shall not apply to the sale of any drug by a manufacturer or wholesaler or pharmacy to each other or to a physician, dentist, veterinarian or other person licensed to prescribe such drugs in their professional practice.

c. Practitioners authorized under the laws of this State to compound drugs and to dispense drugs directly to their patients in the practice of their respective professions shall meet the standards established by their respective licensing boards with respect to storage, handling, security, counseling, labeling, packing and record keeping requirements for the dispensing of drugs, or if no such standards exist, the same storage, handling, security, counseling, labeling, packaging and record keeping requirements for the dispensing of drugs applicable to pharmacists.

45:14–50. License to practice pharmacy

To obtain a license to engage in the practice of pharmacy, the applicant shall:

a. Have submitted a written application in the form prescribed by the board;

b. Have attained the age of 18 years;

c. Be of good moral character;

d. Have graduated and received a professional degree from a college or school of pharmacy that has been approved by the board;

e. Have completed an internship or other program that has been approved by the board, or demonstrated to the board's satisfaction experience in the practice of pharmacy which meets or exceeds the minimum internship requirements of the board;

f. Have successfully passed an examination or examinations as determined by the board; and

g. Have paid the fees specified by the board for the examination and any related materials, and have paid for the issuance of the license.

45:14–51. License examination

The examination for licensure shall measure the competence of the applicant to engage in the practice of pharmacy. The board may employ, cooperate and contract with any organization or consultant in the preparation and grading of an examination, but shall retain the sole discretion and responsibility for determining which applicants have successfully passed the examination.

45:14–52. Practical experience requirements

a. All applicants for licensure by examination shall obtain practical experience in the practice of pharmacy under terms and conditions determined by the board.

b. The board may establish licensure requirements for interns and standards for internship, or any other experiential program necessary to qualify an applicant for the licensure examination, and shall also determine the qualifications of preceptors used in practical experience programs.

45:14–53. Pharmacists licensed in other jurisdictions; license transfer

a. In order for a pharmacist currently licensed in another jurisdiction to obtain a license as a pharmacist by license transfer in this State, an applicant shall:

(1) Have submitted a written application in the form prescribed by the board;

(2) Have attained the age of 18 years;

(3) Have good moral character;

(4) Have engaged in the practice of pharmacy for a period of at least 1, 000 hours within the last two years or have met, immediately prior to application, the internship requirements of this State within the one-year period immediately preceding the date of application;

(5) Have presented to the board proof of initial licensure by examination and proof that the license is in good standing;

(6) Have presented to the board proof that any other license granted to the applicant by any other state has not been suspended, revoked or otherwise restricted for any reason except nonrenewal or for the failure to obtain the required continuing education credits in any state where the applicant is currently licensed but not engaged in the practice of pharmacy;

(7) Have paid the fees specified by the board;

(8) Have graduated and received a professional degree from a college or school of pharmacy approved by the board; and

(9) Have met any other requirements as established by the board by regulation.

b. No applicant shall be eligible for license transfer unless the applicant holds a current valid license in a state that grants licensure transfer to pharmacists duly licensed by examination in this State.

c. In order for a pharmacist applicant with a pharmacy degree from a foreign country or a college of pharmacy not approved by the board to obtain a license as a pharmacist, that applicant shall meet those requirements as established by the board by regulation.

45:14–54. Renewal certification; continuing education

a. The board shall require each person registered as a pharmacist, as a condition for biennial renewal certification, to complete continuing pharmacy education during each biennial period immediately preceding the date of renewal and submit proof thereof to the board.

b. The board shall:

(1) Establish standards for continuing pharmacy education, including thenumber of credits, the subject matter and content of courses of study, the selection of instructors and the type of continuing education credits required of a registered pharmacist as a condition of biennial registration;

(2) Approve educational programs offering credit towards continuing pharmacy education requirements; and

(3) Approve other equivalent educational programs, including, but not limited to, home study courses, and establish procedures for the issuance of credit upon satisfactory proof of the completion of these programs. In the case of continuing education courses and programs, each hour of instruction shall be equivalent to one credit.

c. (1) The board shall only approve programs that are provided on a nondiscriminatory basis. The board shall permit any pharmacy association or organization offering a continuing pharmacy education program approved by the board pursuant to subsection b. of this section to impose a reasonable differential in registration fees for courses upon registered pharmacists who are not members of that pharmacy association or organization. The board may approve programs held within or outside the State.

(2) In no event shall the board grant credits for, or approve as, a component of a continuing education program:

(a) participation in a routine business portion of a meeting of a pharmacy association or organization; or

(b) any presentation that is offered to sell a product or promote a business enterprise.

d. (1) The board may, in its discretion, waive requirements for continuing education on an individual basis for reasons of hardship, such as illness or disability, retirement of the registration certificate, or any other good cause.

(2) The board shall not require completion of continuing education credits for an initial renewal of registration.

(3) If a pharmacist completes a number of continuing education credit hours in excess of the number required for a biennial period, the board may allow, by rule or regulation, credits to be carried over to satisfy the pharmacist's continuing education requirement for the next biennial renewal period, but shall not be applicable thereafter.

45:14–55. Practitioners; prescription blanks; record of receipt

a. A practitioner practicing in this State shall use non- reproducible, non-erasable safety paper New Jersey Prescription Blanks bearing that practitioner's license number whenever the practitioner issues prescriptions for controlled dangerous substances, prescription legend drugs or other prescription items. The prescription blanks shall be secured from a vendor approved by the Division of Consumer Affairs in the Department of Law and Public Safety.

b. A licensed practitioner practicing in this State shall maintain a record of the receipt of New Jersey Prescription Blanks. The practitioner shall notify the Office of Drug Control in the Division of Consumer Affairs as soon as possible but no later than 72 hours of being made aware that any New Jersey Prescription Blank in the practitioner's possession has been stolen. Upon receipt of notification, the Office of Drug Control shall take appropriate action, including notification to the Department of Human Services and the Attorney General.

45:14–56. Health care facilities; prescription blanks; record of receipt

a. Prescriptions issued by a health care facility licensed pursuant to P.L.1971, c. 136 (C.26:2H–1 et seq.) shall be written on non-reproducible, non-erasable safety paper New Jersey Prescription Blanks. The prescription blanks shall be secured from a vendor approved by the Division of Consumer Affairs in the Department of Law and Public Safety. The New Jersey Prescription Blanks shall bear the unique provider number assigned to that health care facility for the issuing of prescriptions for controlled dangerous substances, prescription legend drugs or other prescription items.

b. A health care facility shall maintain a record of the receipt of New Jersey Prescription Blanks. The health care facility shall notify the Office of Drug Control in the Division of Consumer Affairs as soon as possible but no later than 72 hours of being made aware that any New Jersey Prescription Blank in the facility's possession has been stolen. Upon receipt of notification, the Office of Drug Control shall take appropriate action including notification to the Department of Human Services and the Attorney General.

45:14–57. Practitioner's license number or provider number required on prescription

A prescription issued by a practitioner or health care facility licensed in New Jersey shall not be filled by a pharmacist unless the prescription is issued on a New Jersey Prescription Blank bearing the practitioner's license number or the unique provider number assigned to a health care facility.

45:14–58. Prescriptions transmitted by telephone or electronic means; controlled substances

a. Nothing contained in this act shall preclude a practitioner from transmitting to a pharmacist by telephone or electronic means a prescription, as otherwise authorized by law, if that practitioner provides the practitioner's Drug Enforcement Administration registration number and the practitioner's license number, or any other federally identified number, as appropriate, to the pharmacist at the time the practitioner transmits the prescription.

b. Except as may be otherwise permitted by law, no prescription for any Schedule II controlled dangerous substance shall be given or transmitted to pharmacists, in any other manner, than in writing signed by the practitioner giving or transmitting the same, nor shall such prescription be renewed or refilled. The requirement in this subsection that a prescription for any controlled dangerous substance be given or transmitted to pharmacists in writing signed by the practitioner shall not apply to a prescription for a Schedule II drug if that prescription is transmitted or prepared in compliance with federal and State regulations.

45:14–59. Format for New Jersey Prescription Blanks

The Division of Consumer Affairs in the Department of Law and Public Safety shall establish the format for uniform, non-reproducible, non-erasable safety paper prescription blanks, to be known as New Jersey Prescription Blanks, which format shall include an identifiable logo or symbol that will appear on all prescription blanks. The division shall approve a sufficient number of vendors to ensure production of an adequate supply of New Jersey Prescription Blanks for practitioners and health care facilities statewide.

45:14–60. Dispensation of different dosage form than originally prescribed

A pharmacist may dispense a prescription in a different dosage form than originally prescribed if the pharmacist notifies the prescriber no later than 48 hours following the dispensing of the prescription, provided the dosage form dispensed has the appropriate drug release rate.

45:14–61. Collaborative practice requirements

In establishing requirements for pharmacists to engage in collaborative practice as provided in paragraph (4) of subsection a. of section 9 of this act[1], the board shall include in these requirements, but not be limited to, provisions that any written protocol between a physician and pharmacist:

a. is agreed to by both the physician and the pharmacist with the consent of the patient;

b. identifies, by name and title, each physician and each pharmacist who is permitted to participate in a patient's collaborative drug therapy management;

c. specifies the functions and responsibilities the pharmacist will be performing;

d. is available at the practice sites of the pharmacist and physician and made available at each site to the patient;

e. is initiated and utilized at the sole discretion of the physician for a specific patient;

f. may be terminated at any time by either party by written documentation;

g. establishes when physician notification is required, the physician chart update interval, and an appropriate time frame within which the pharmacist must notify the physician of any change in dose, duration or frequency of medication prescribed;

h. remains in effect for a period not to exceed two years upon the conclusion of which, or sooner, the parties shall review the protocol and make a determination as to its renewal, modification or termination; and

i. establish the means by which the patient will be advised of the right to elect to participate in and withdraw from the collaborative drug therapy management.

[1]N.J.S.A. 45:14–48.

45:14–62. Collaborative drug therapy management

a. Each collaborative drug therapy management shall be between a single patient's specific physician and the patient's pharmacist or pharmacy and address that patient's specific condition, disease or diseases.

b. No collaborative drug therapy management shall include, without the prior consent of the patient and the patient's physician who has signed the protocol, therapeutic interchange at the time of dispensing, provided that written confirmation of this prior consent, which may be by electronic means, shall be obtained pursuant to record keeping guidelines to be established by regulation jointly promulgated by the board and the State Board of Medical Examiners.

45:14–63. Medications administered for treatment of disease; nationally certified programs; immunization programs and programs sponsored by government agencies

a. No pharmacist shall administer a prescription medication directly to a patient without appropriate education or certification, as determined by the board in accordance with the requirements set forth in the rules jointly promulgated by the board and the State Board of Medical Examiners. Such medication shall only be for the treatment of a disease for which a nationally certified

program is in effect, or as determined by the board, and only if utilized for the treatment of that disease for which the medication is prescribed or indicated or for which the collaborative drug therapy management permits.

b. Notwithstanding any law, rule or regulation to the contrary, other than for pediatric immunizations, a pharmacist may administer drugs in immunization programs and programs sponsored by governmental agencies that are not patient specific provided the pharmacist is appropriately educated and qualified, as determined by the board in accordance with the requirements set forth in the rules jointly promulgated by the board and the State Board of Medical Examiners.

45:14–64. Act not applicable to pharmacist practicing in hospital

The provisions of this act regulating collaborative drug therapy management shall not apply to any pharmacist practicing in a hospital, provided that prescribing within these institutions takes place under the guidance of a pharmacy and therapeutics committee in accordance with procedures as determined by regulations jointly promulgated by the board and the State Board of Medical Examiners.

45:14–65. Unprofessional conduct; penalties

In addition to the provisions of section 8 of P.L.1978, c. 73 (C.45:1–21), the board may refuse an application for examination or may suspend or revoke the certificate of a licensed pharmacist upon proof satisfactory to the board that such licensed pharmacist is guilty of grossly unprofessional conduct and the following acts are hereby declared to constitute grossly unprofessional conduct for the purpose of this act:

a. Paying rebates or entering into an agreement for payment of rebates to any physician, dentist or other person for the recommending of the services of any person.

b. The providing or causing to be provided to a physician, dentist, veterinarian or other person authorized to prescribe, prescription blanks or forms bearing the pharmacist's or pharmacy's name, address or other means of identification.

c. The claiming of professional superiority in the compounding or filling of prescriptions or in any manner implying professional superiority which may reduce public confidence in the ability, character or integrity of other pharmacists.

d. Fostering the interest of one group of patients at the expense of another which compromises the quality or extent of professional services or facilities made available.

e. The distribution of premiums or rebates of any kind whatsoever in connection with the sale of drugs and medications provided, however, that trading stamps and similar devices shall not be considered to be rebates for the purposes of this act and provided further that discounts, premiums and rebates may be provided in connection with the sale of drugs and medications to any person who is 60 years of age or older.

f. Advertising of prescription drug prices in a manner inconsistent with rules and regulations promulgated by the Director of the Division of Consumer Affairs, except that no advertising of any drug or substance shall be authorized unless the Commissioner of Health and Senior Services shall have determined that the advertising is not harmful to public health, safety and welfare.

g. Engaging in activities beyond the scope of a collaborative drug therapy management agreement. Before a certificate shall be refused, suspended or revoked, the accused person shall be furnished with a copy of the complaint and given a hearing before the board. Any person whose

certificate is so suspended or revoked shall be deemed an unlicensed person during the period of such suspension or revocation, and as those shall be subject to the penalties prescribed in this act, but that person may, at the discretion of the board, have his certificate reinstated at any time without an examination, upon application to the board. Any person to whom a certificate shall be denied by the board or whose certificate shall be suspended or revoked by the board shall have the right to review that action by appeal to the Appellate Division of the Superior Court in lieu of prerogative writ.

45:14–66. Drug utilization review

a. A pharmacist shall conduct a drug utilization review before each new medication is dispensed or delivered to a patient.

b. A pharmacist shall conduct a prospective drug utilization review in accordance with the provisions of this section before refilling a prescription or medication order to the extent he deems appropriate in his professional judgment.

c. A pharmacist shall exercise independent professional judgment as to whether or not to dispense or refill a prescription or medication order. In determining to dispense or refill a prescription or medication order, the decision of the pharmacist shall not be arbitrary but shall be based on professional experience, knowledge or available reference materials.

45:14–67. Offer to counsel

A pharmacist or his designee shall offer to provide counseling to any person who presents a new prescription in a manner as determined pursuant to criteria established by the board.

45:14–68. Patient profile system

a. A patient profile system shall be maintained by all pharmacies for persons for whom medications are dispensed. The patient profile record system shall enable the dispensing pharmacist to identify previously dispensed medication at the time a prescription is presented for dispensing.

b. The following information generated or transferred to the individual pharmacy practice site shall be recorded in the patient profile system:

(1) The family and the first name of the person for whom the medication is intended (the patient);

(2) The street address and telephone number of the patient;

(3) Indication of the patient's age, birth date or age group (infant, child, adult) and gender;

(4) The height, weight and other patient specific criteria for those medications that are height or weight dose dependent;

(5) The original or refill date the medication is dispensed and the initials of the dispensing pharmacist, if those initials and date are not recorded on the original prescription or in any other record approved by the board;

(6) The number or designation identifying the prescription;

(7) The practitioner's name;

(8) The name, strength and quantity of the drug dispensed;

(9) The individual history, if significant, including known allergies and drug reactions, known diagnosed disease states and a comprehensive list of medications and relevant devices; and

(10) Any additional comments relevant to the patient's drug use, which may include any failure to accept the pharmacist's offer to counsel.

c. The information obtained shall be recorded in the patient's manual or electronic profile, or in the prescription signature log, or in any other system of records, and may be considered by the pharmacist in the exercise of his professional judgment concerning both the offer to counsel and content of counseling. The absence of any record of a failure to accept the pharmacist's offer to counsel shall be presumed to signify that the offer was accepted and that the counseling was provided.

45:14–69. Permit for pharmacy practice sites

a. All pharmacy practice sites in this State, which engage in the practice of pharmacy in the State of New Jersey, shall be issued a permit by the board, and shall annually renew their permit with the board. If operations are conducted at more than one location, each location shall be issued a permit by the board for the dispensing of medicine.

b. The board may determine by rule or regulation the permit classifications of all pharmacy practice sites issued a permit under this act, and establish minimum standards for pharmacy practice sites.

c. The board shall establish by rule or regulation the criteria which each site shall meet to qualify for a permit in each classification. The board may issue permits with varying restrictions to pharmacy practice sites if the board deems it necessary.

d. Each holder of a pharmacy practice site permit shall ensure that a licensed pharmacist be immediately available on the premises to provide pharmacy services at all times the pharmacy practice site is open.

e. Each pharmacy practice site shall have a pharmacist-in-charge. The pharmacist-in-charge and the owner of a pharmacy practice site shall be responsible for any violation of any laws or regulations pertaining to the practice of pharmacy.

f. The board may enter into agreements with other states or with third parties for the purpose of exchanging information concerning the granting of permits and the inspection of pharmacy practice sites located in this State and those located outside this State.

g. The board may deny, suspend, revoke, restrict or refuse to renew a permit for a pharmacy practice site that does not comply with the provisions of this act or any rule or regulation promulgated pursuant to this act.

45:14–70. Permit application procedures

a. The board shall specify by rule or regulation the permit application procedures to be followed, including, but not limited to, the specification of forms to be used, the time and place the application is to be made and the fees to be charged.

b. Applicants for a permit to operate a pharmacy practice site within this State shall file with the board a verified application containing the information that the board requires of the applicant relative to the qualifications for the specific permit.

c. The board shall specify, by rule or regulation, minimum standards for any pharmacy practice site within this State. Pharmacy practice sites located in New Jersey shall be operated at all times under the immediate supervision of a pharmacist licensed to practice in this State.

d. Permits issued by the board pursuant to this act shall not be transferable or assignable without the approval of the board.

45:14–71. Use of "pharmacy" or words of similar meaning in course of business

No person shall carry on, conduct or transact business under a name which contains as a part thereof the words ''pharmacist,'' '' pharmacy,'' ''apothecary,'' ''apothecary shop,'' ''druggist,'' '' drug'' or any word or words of similar or like import, or in any manner by advertisement, circular, poster, sign or otherwise describe or refer to the place of business by the terms ''pharmacy,'' ''apothecary,'' ''apothecary shop,'' ''chemist's shop,'' ''drug store,'' ''drugs'' or any word or words of similar or like import unless the place of business is a currently licensed pharmacy practice site operatedor managed at all times by a pharmacist.

45:14–72. Non-prescription drug sales

This act shall not prohibit, restrict or otherwise interfere with the sale of non-prescription drugs and devices at places other than a pharmacy practice site or by persons in this State who are not licensed pharmacists.

45:14–73. Out-of-state pharmacies; registration

Any pharmacy located in another state which ships, mails, distributes or delivers in any manner, legend drugs or devices pursuant to a prescription into this State, shall register with the board and provide the board with the following information:

(1) The location, names and titles of all principal corporate officers of the pharmacy. A report containing this information shall be made on an annual basis and within 30 days after any change of office or corporate officer; and

(2) That it complies with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is licensed as well as with all requests for information made by the board pursuant to this section. As a prerequisite to registering with the board, the pharmacy shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which it is located.

The annual registration fee shall be established by the board and shall not exceed $500 annually.

Any pharmacy subject to this section shall, during its regular hours of operation, but not less than six days per week, and for a minimum of 40 hours per week, provide a toll-free telephone service to facilitate communication between patients in this State and a pharmacists at a pharmacy who has access to the patient's records. This toll-free number shall be disclosed on a label affixed to each container of drugs dispensed to patients in this State.

45:14–74. Mandatory reporting by licensed pharmacy practice

a. All licensed pharmacy practice sites shall report to the board the occurrences of any of the following:

(1) Closing of the pharmacy practice site;

(2) Change of ownership, location, interior site design, permit classification or pharmacist-in-charge of the pharmacy practice site;

(3) Any significant theft or loss of legend drugs or devices;

(4) Disasters, accidents, any theft, destruction or loss of records required to be maintained by State or federal law;

(5) Any pharmacy malpractice liability insurance claim settlement, judgment or arbitration award in excess of $10,000 to which an owner, an employee of, or the pharmacy practice site itself is a party; and

(6) Any and all other matters and occurrences as the board may require by rule or regulation.

b. The manner, time and content of the notification shall be prescribed by rule or regulation by the board.

45:14–75. Permit to operate pharmacy

a. No pharmacy practice site shall operate until it has been issued a permit by the board.

b. The board may suspend, revoke, deny, restrict or refuse to renew the permit of any pharmacy practice site on any of the following grounds:

(1) Findings by the board that any conduct of the permit holder or applicant is violative of any federal, State or local laws or regulations relating to the practice of pharmacy;

(2) A conviction of the permit holder or applicant under federal, State or local laws for a crime of moral turpitude or a crime that relates adversely to the practice of pharmacy;

(3) Materially false or fraudulent information contained within any application made to the board or in any application relating to drug or device prescribing, dispensing or administration;

(4) Suspension or revocation by federal, State or local government of any license or permit relating to the practice of pharmacy currently or previously held by the applicant or permit holder;

(5) Utilizing a permit to obtain remuneration by fraud, misrepresentation or deception;

(6) Dealing with drugs or devices that are known or should have been known as stolen drugs or devices;

(7) Purchasing or receiving of a drug or device by a permit holder or for use at a pharmacy practice site from a source that is not licensed under the laws of the State, except where otherwise provided;

(8) Intensive and ongoing failure to provide additional personnel, automation and technology as is necessary to ensure that the licensed pharmacist on duty has sufficient time to utilize the professional's knowledge and training and to competently perform the functions of a licensed pharmacist as required by law;

(9) Violation of any of the provisions of the ''New Jersey Controlled Dangerous Substance Act,'' P.L.1970, c. 226 (C.24:21–1 et seq.) by the applicant, permit holder or occurring at the pharmacy practice site; or

(10) Violations of any of the provisions of P.L.1978, c. 73 (C.45:1–14 et seq.) by the applicant, permit holder or occurring at the pharmacy practice site.

c. Reinstatement of a permit that has been suspended or restricted by the board may be granted in accordance with the procedures specified by the board.

45:14–76. Data privacy

Pharmacists and pharmacies shall comply with the provisions of the federal Standards of Practice of Individually Identifiable Health Information, 45 C.F.R. Parts 160 and 164.

45:14–77. Immunity for reporting misconduct

A person who in good faith and without malice provides to the board any information concerning any act by a pharmacist licensed by the board which the person has reasonable cause to believe involves misconduct that may be subject to disciplinary action by the board, or any information relating to such conduct requested by the board in the exercise of its statutory responsibilities or which may be required by statute, shall not be liable for civil damages in any cause of action arising out of the provision of such information or services.

45:14–78. Grandfather clause

a. Any person who is licensed in this State as a pharmacist on the effective date of this act may continue to practice under his current license until its expiration, and to obtain a license under this act without examination upon payment of a fee.

b. Any site with a permit in this State as a pharmacy practice site on the effective date of this act may continue to operate under its current permit until its expiration.

45:14–79. Effect upon prior rules and regulations

This act shall not affect the orders, rules and regulations regarding the practice of pharmacy made or promulgated by the board created pursuant to R.S.45:14–1 et seq. prior to the effective date of this act.

45:14–80. Pharmacy technicians

a. Pharmacy technicians may assist a licensed pharmacist in performing the following tasks:

(1) Retrieval of prescription files, patient files and profiles and other records, as determined by the board, pertaining to the practice of pharmacy;

(2) Data entry;

(3) Label preparation; and

(4) Counting, weighing, measuring, pouring and compounding of prescription medication or stock legend drugs and controlled substances, including the filling of an automated medication system.

b. Pharmacy technicians may accept authorization from a patient for a prescription refill, or from a physician or the physician's agent for a prescription renewal, provided that the prescription remains unchanged. As used in this section, ''prescription refill'' means the dispensing of medications pursuant to a prescriber's authorization provided on the original prescription and ''prescription renewal'' means the dispensing of medications pursuant to a practitioner's authorization to fill an existing prescription that has no refills remaining.

c. Pharmacy technicians shall not:

(1) Receive new verbal prescriptions;

(2) Interpret a prescription or medication order for therapeutic acceptability and appropriateness;

(3) Verify dosage and directions;

(4) Engage in prospective drug review;

(5) Provide patient counseling;

(6) Monitor prescription usage;

(7) Override computer alerts without first notifying the pharmacist;

(8) Transfer prescriptions from one pharmacy to another pharmacy; or

(9) Violate patient confidentiality.

d. Except as provided in subsection e. of this section, a pharmacist shall not supervise more than two pharmacy technicians.

e. A pharmacy that wishes to employ a licensed pharmacist to pharmacy technician ratio greater than established in accordance with subsection d. of this section, shall:

(1) Establish written job descriptions, task protocols and policies and procedures that pertain to the duties performed by the pharmacy technician;

(2) Ensure and document that each pharmacy technician pass the National Pharmacy Technician Certification Examination or a board approved certification program and fulfill the requirements to maintain this status, or complete a program which includes a testing component and which has been approved by the board as satisfying the criteria as set forth in subsection f. of this section;

(3) Ensure that each pharmacy technician is knowledgeable in the established job descriptions, task protocols and policies and procedures in the pharmacy setting in which the technician is to perform his duties;

(4) Ensure that the duties assigned to any pharmacy technician do not exceed the established job descriptions, task protocols and policies and procedures;

(5) Ensure that each pharmacy technician receives in-service training before the pharmacy technician assumes his responsibilities and maintain documentation thereof;

(6) Require and maintain on site a signed patient confidentiality statement from each technician;

(7) Provide immediate personal supervision; and

(8) Provide the board, upon request, with a copy of the established job descriptions, task protocols and policies and procedures for all pharmacy technician duties.

f. If the pharmacist to pharmacy technician ratio is greater than the ratio established in accordance with the provisions of subsection d. of this section, the pharmacy shall maintain a policy and procedure manual with regard to pharmacy technicians, which shall include the following:

(1) Supervision by a pharmacist;

(2) Confidentiality safeguards of patient information;

(3) Minimum qualifications;

(4) Documentation of in-service education or ongoing training and demonstration of competency, specific to practice site and job function;

(5) General duties and responsibilities of pharmacy technicians;

(6) Retrieval of prescription files, patient files, patient profile information and other records pertaining to the practice of pharmacy;

(7) Functions related to prescription processing;

(8) Functions related to prescription legend drug and controlled dangerous substance ordering and inventory control;

(9) Prescription refill and renewal authorization;

(10) Procedures dealing with documentation and records required for controlled dangerous substance and prescription legend drugs;

(11) Procedures dealing with medication errors;

(12) Pharmacy technician functions related to automated systems;

(13) Functions that may not be performed by pharmacy technicians; and

(14) A form signed by the pharmacy technician which verifies that the manual has been reviewed by the technician.

g. The pharmacist in charge shall review the policy and procedure manual at least every two years and, if necessary, amend the manual as needed. Documentation of the review shall be made available to the board upon request.

h. Pharmacy technicians shall wear an identification tag, which shall include at least their first name, the first initial of their last name and title.

i. On pharmacy permit renewal applications, the pharmacy shall list the name and address of all pharmacy technicians which it currently employs.

j. When pharmacy technicians are engaged in any activities permitted in accordance with the provisions of this section, the licensed pharmacists on site shall be responsible for these activities.

BOARD OF PHARMACY

CHAPTER 39. STATE BOARD OF PHARMACY

SUBCHAPTER 1. GENERAL PROVISIONS

13:39–1.1 Purpose and scope

(a) This chapter is promulgated by the New Jersey State Board of Pharmacy. The rules contained in this chapter implement the provisions of the Pharmacy Act, N.J.S.A. 45:14–1 et seq. and regulate the practice of pharmacy within the State of New Jersey.

(b) This chapter shall apply to all registered pharmacies, pharmacists, pharmacist applicants, interns, externs, pharmacy technicians and anyone within the jurisdiction of the Board of Pharmacy.

13:39–1.2 Definitions

The following words and terms when used in this chapter shall have the following meanings, unless the context clearly indicates otherwise.

''Address of record'' means an address designated by a licensee. ''Address of record'' may be a licensee's home, business or mailing address, but shall not be a post office box unless the licensee also provides another address which includes a street, city, state and zip code.

''Authorized prescriber'' means a licensed practitioner who is authorized by law to write prescriptions and/or medication orders.

''Board'' means the New Jersey State Board of Pharmacy.

''Compounding'' means the act of preparing pharmaceutical components into medications, pursuant to an authorized prescriber's prescription or medication order, including, but not limited to prescription compounding, and intravenous admixture preparation.

''Device'' means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including any component part or accessory, which is required under Federal or State law to be prescribed by an authorized prescriber and dispensed by a pharmacist, in the usual scope of pharmacy practice.

''Dispense or dispensing'' means the procedure entailing the interpretation of an authorized prescriber's prescription order for a drug or device, and pursuant to that order, the proper selection, measuring, labeling, and packing in a proper container. The act of dispensing shall include all necessary consultation by the pharmacist.

''Drug or medicine'' means:

1. Articles recognized in the official United States Pharmacopoeia/ National Formulary, official Homeopathic Pharmacopoeia of the United States, or any official supplement to any of them;
2. Articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in human beings or animals;
3. Articles (other than food) intended to affect the structure of any function of the body of human beings or animals; and

4. Articles intended for use as components of any article specified in 1, 2 or 3 above, but not including devices or their components, parts or accessories.

''Immediate personal supervision'' means that the registered pharmacist is physically present in the compounding/dispensing area when interns, externs and pharmacy technicians are performing delegated duties, and the pharmacist conducts any necessary in-process checks and the final check in preparation and compounding of medications, including the checking of each ingredient used, the quantity of each ingredient whether weighed, measured or counted, and the finished label.

''Legend drug or device'' means any drug or device that:

1. Bears, at a minimum, the symbol ''Rx only'' or words of similar import; and/or

2. Requires a prescription or order by an authorized prescriber.

''Licensed practitioner'' means a duly licensed physician, dentist, optometrist, veterinarian, certified nurse midwife, nurse practitioner/clinical nurse specialist or physician assistant, or other health care practitioner licensed or approved to write prescriptions intended for the treatment or prevention of disease, as set forth in N.J.S.A. 45:14–14.

''Pharmaceutical services'' means all services provided by a registered pharmacist. These services shall be concerned with, but not limited to: interpreting the prescription or medication order; selecting, preparing, compounding, packaging, labelling, distributing and dispensing prescribed drugs; the proper and safe storage of drugs; the monitoring of drug therapy; the reporting and recording of adverse drug reactions and the provision of appropriate drug information; teaching and counselling on the proper and safe use of drugs and medications.

''Pharmacy technician'' means an individual employed by a pharmacy whose responsibilities do not require professional judgment in the preparation and distribution of medications and who works under the immediate personal supervision of a pharmacist in compliance with N.J.A.C. 13:39–6.6. For purposes of this definition, interns, externs, cashiers, stocking and clerical help are not pharmacy technicians.

''Prescription'' means any order for drugs and related items as defined in N.J.S.A. 45:14–14.

''Professional judgment'' means judiciousness and discretion based upon thorough knowledge and sound application of the specialized body of knowledge peculiar to the practice of pharmacy, and an understanding of the relationship of this knowledge and its application to the well-being of the patient and to the judgment of the prescriber.

''Registered pharmacist'' or ''pharmacist'' means a person whose license is in good standing for the current license renewal period.

13:39–1.3 Fee schedule

(a) The following fees shall be charged by the Board:

1. For pharmacists as follows:

i. Application for licensure	$125.00.
ii. Verification of licensure	$25.00.
iii. Application for reciprocity	$125.00.

iv. Application for reinstatement

(1) Disciplinary suspension	$225.00.
(2) Administrative suspension	(To be determined by future rulemaking)
v. Initial licensure fee	
(1) If paid during the first year of a biennial renewal period	$140.00.
(2) If paid during the second year of a biennial renewal period	$70.00.
vi. Biennial license renewal	$140.00.
vii. Replacement biennial license	$25.00.
viii.Inactive license renewal	(To be determined by future rulemaking)
ix. Late renewal fee	$100.00.
x. Replacement of initial wall license	$40.00.
xi. Continuing education review fee	$10.00.
xii. Continuing education program or course: sponsor review fee	$50.00.
xiii. Yearly fee for distribution of minutes and agenda	$60.00.

2. For pharmacies as follows:

i. Pharmacy permits

(1) Application for permit	$275.00.
(2) Annual permit renewal	$175.00.
(3) Change of ownership/name	$275.00.
(4) Change of location	$275.00.
ii. Replacement of annual permit	$25.00.
iii. Late renewal fee	$100.00.
iv. Verification of permit	$25.00.

13:39–1.4 Payment of penalties

(a) Any penalties levied by the Board shall be paid within 10 calendar days of the finalization of a penalty letter or final order of the Board unless otherwise prescribed by statute or terms of a final order.

(b) Failure to comply with this rule may result in action by the Board according to the provisions of N.J.S.A. 45:1–24.

13:39–1.5 Opportunity to be heard

(a) Any time the Board seeks to impose a disciplinary sanction upon a licensee, the licensee may request an opportunity to be heard by the Board.

(b) When demonstrated facts are in dispute, a hearing shall be conducted pursuant to the Administrative Procedure Act, N.J.S.A. 52:14B–1 et seq., and the Uniform Administrative Procedure Rules, N.J.A.C. 1:1.

SUBCHAPTER 2. LICENSURE REQUIREMENTS

13:39–2.1 Examinations; score

(a) The examination for licensure by the Board shall be the North American Pharmacist Licensure Examination (NAPLEX). An applicant shall attain a passing score of not less than 75. If an applicant fails the examination, he or she shall be required to repeat the examination.

(b) The applicant shall also pass the Multistate Jurisprudence Pharmacy Examination (MJPE). A passing score of not less than 75 shall be attained. If an applicant fails the examination, he or she shall be required to repeat the examination.

(c) If the applicant should fail either the NAPLEX or the MJPE three times, the Board may direct the applicant to take remedial courses at an accredited school or college of pharmacy prior to retaking the failed examination(s).

13:39–2.2 Education requirements

(a) An applicant for the NAPLEX and MJPE examinations shall have been duly granted or have fully completed all the requirements for graduation of a minimum five-year pharmacy course leading to a degree of Bachelor of Science in pharmacy or Doctor of Pharmacy given in a school or college of pharmacy accredited by the American Council of Pharmaceutical Education (ACPE).

(b) Before being admitted to the NAPLEX AND MJPE examinations, either a transcript of the applicant's record or a certificate by the registrar of the school or college of pharmacy attended must be supplied stating that the applicant has either graduated or has completed all of the requirements for graduation. If the transcript or certificate does not state that the applicant has graduated or has completed all the graduation requirements, the Board may require other forms of proof to be supplied by the applicant.

13:39–2.3 Application for examinations

An applicant for the NAPLEX and MJPE examinations shall file an application for such examinations at least 30 days prior to the date of the respective examination unless the 30–day requirement is waived by the Board because of extenuating circumstances. The application fee set forth in N.J.A.C. 13:39–1.3 shall also be submitted.

13:39–2.4 Age requirement

An applicant who is not of legal age, that is, the age of majority in the State of New Jersey, but who has otherwise met the application requirements, with the exception of the internship requirement, may be admitted to the NAPLEX and MJPE examinations; however, the applicant shall not be eligible for licensure until attaining legal age.

13:39–2.5 Proof of character

(a) An applicant for the NAPLEX and MJPE examinations shall submit, in advance, an application containing evidence of good moral character which is an ongoing requirement for licensure, and evidence that he or she:

1. Is not presently engaged in drug or alcohol use that is likely to impair the ability to practice pharmacy with reasonable skill and safety. For purposes of this section, the term ''presently'' means at this time or any time within the previous 365 days;
2. Has not been convicted of violating any law of this State or any other state of the United States relating to controlled dangerous substances or other habit-forming drugs;
3. Has not been convicted of violating any law relating to the practice of pharmacy;
4. Has not been convicted of a crime involving moral turpitude; and
5. Has not had his or her license or, if a permit holder, his or her permit, suspended or revoked in the last five years as a result of any administrative or disciplinary proceedings in this or any other jurisdiction which proved the applicant to be in violation of any laws, rules or regulations pertaining to the practice of pharmacy, and that the applicant is not currently under suspension or revocation.

13:39–2.6 Criminal history background check

An applicant for initial licensure as a pharmacist in the State shall submit his or her name, address and fingerprints for purposes of a criminal history background check to be conducted by the State of New Jersey pursuant to N.J.S.A. 45:1–28 et seq., P.L. 2002, c. 104, to determine whether criminal history record information exists which may be considered by the Board in determining whether the applicant shall be licensed in the State.

13:39–2.7 Proof of identity of applicant

An applicant for the NAPLEX and MJPE examinations shall submit to the Board 30 days in advance of the date of the examinations a passport photograph mounted on a document to be supplied by the Board requesting certain identification information.

13:39–2.8 Alleged violations of the Pharmacy Act

If an applicant for any Board examination is being investigated for any alleged violation of the Pharmacy Act, N.J.S.A. 45:14–1 et seq., the Board in its discretion may deny the applicant the opportunity to take the examination.

13:39–2.9 Applicants educated in a foreign country

(a) Any pharmacist applicant with a degree from a country where theprimary language is other than English, prior to being granted initiallicensure as a professional pharmacist in this State, shall submit to theBoard evidence that he or she has been certified within two years ofapplying for licensure in the State by the Foreign Pharmacy GraduateExamination Committee (FPGEC) of the National Association of Boardsof Pharmacy.

(b) Any pharmacist applicant with a degree from a country other than the United States, where the primary language is English, prior to being granted initial licensure as a professional pharmacist in this State, shallsubmit to the Board evidence that he or she has successfully completed the Foreign Pharmacy Graduate Equivalency Examination (FPGEE).

(c) A request for waiver of the FPGEC certificate shall delineate good cause for the waiver request. The Board may, after due consideration and within its own discretion, waive the TOEFL examination and the Test of Spoken English (TSE) examination components of the FPGEC certification process.

(d) Notwithstanding (a) through (c) above, the provisions of this section shall not apply to any pharmacist applicant who has graduated from a pharmacy school which has been accredited by the American Council of Pharmaceutical Education (ACPE), or has graduated from a pharmacy school that has been accredited by a program that has been deemed ACPEequivalent by ACPE.

13:39–2.10 Authorization to practice; display of license

(a) An applicant who has successfully satisfied all Board requirements for licensure and has been approved by the Board to be licensed shall receive an authorization signed by the Executive Director of the Board granting the applicant the right to practice pharmacy in the State of New Jersey until such time as an initial license may be issued. The licensee shall maintain such authorization on his or her person at all times while engaging in the practice of pharmacy until the initial license is issued.

(b) Upon issuance of a license, the initial wall license and current biennial renewal license shall be conspicuously displayed in the registered pharmacist's principal place of employment.

(c) A registered pharmacist who is employed by more than one licensed pharmacy in the State shall maintain the wallet-sized license issued by the Board on his or her person when he or she is working at a location where his or her wall license and current biennial renewal license are not on display.

13:39–2.11 Replacement license

A replacement initial license or renewal license shall be issued by the Board upon payment of a fee as prescribed in N.J.A.C. 13:39–1.3 and upon submission of proof of the applicant's identity and reasonable proof of the loss or destruction of the initial license or renewal license, or upon return of the damaged initial license or renewal license to the Board.

13:39–2.12 Change of name

If a registered pharmacist legally changes the name under which he or she engages in the practice of pharmacy, the pharmacist shall notify the Board within 30 days of such change. The registered pharmacist shall submit original proof of the change of name or a certified copy of the court order or marriage certificate which shall be retained by the Board. When a replacement license is issued, the initial license shall be returned for cancellation and the pharmacist shall remit the required fee as prescribed in N.J.A.C. 13:39–1.3.

13:39–2.13 Change of address of record; service of process

(a) A registered pharmacist shall notify the Board in writing of any change in his or her address of record within 30 days.

(b) Failure to notify the Board of any change in a registered pharmacist's address of record pursuant to (a) above may result in disciplinary action in accordance with N.J.S.A. 45:1–21(h) and N.J.A.C. 13:45C–1.3, and the imposition of penalties set forth in N.J.S.A. 45:1–25.

(c) Service of any administrative complaint or other Board-initiated process at a registered pharmacist's address of record shall be deemed adequate notice for the purposes of N.J.A.C. 1:1–7.1 and the commencement of any disciplinary proceedings.

13:39–2.14 Verification of licensure

A verification that the license of a registered pharmacist is in good standing shall be supplied by the Board upon written request and upon payment of the fee set forth in N.J.A.C. 13:39–1.3.

13:39–2.15 Reproduction of initial license prohibited

The initial wall license, biennial license or wallet-sized license issued by the Board to any pharmacist shall not be reprinted, photographed, photostated, duplicated or reproduced by any other means either in whole or in part, except as provided in N.J.A.C. 13:39–2.11.

13:39–2.16 Biennial license renewal; administrative suspension

(a) A pharmacist shall renew his or her license for a period of two years from the last expiration date. The pharmacist shall submit a renewal application to the Board, along with the renewal fee set forth in N.J.A.C. 13:39–1.3, prior to the date of license expiration. A pharmacist who submits a renewal application within 30 days following the date of license expiration shall submit the renewal fee, as well as the late fee set forth in N.J.A.C. 13:39–1.3. A pharmacist who fails to submit a renewal application within 30 days of license expiration shall have his or her license suspended without a hearing. Such suspension shall be deemed an administrative suspension.

(b) A pharmacist who continues to engage in the practice of pharmacy with a suspended license shall be deemed to be engaging in the unauthorized practice of pharmacy and shall be subject to the penalties set forth in N.J.S.A. 45:1–25 et seq.

(c) The Board shall send a notice of renewal to each pharmacist at least 60 days prior to the expiration of the license. If the notice to renew is not sent at least 60 days prior to the expiration date, no monetary penalties or fines shall be imposed upon the pharmacist for failure to renew.

13:39–2.17 Reinstatement from administrative and disciplinary license suspensions

(a) A pharmacist who has had his or her license administratively suspended pursuant to N.J.A.C. 13:39–2.16 may apply to the Board for reinstatement within five years following the date of license expiration. A pharmacist applying for reinstatement shall submit:

1. A renewal application, including an affidavit of employment listing each job held during the period of license suspension, including the names, addresses, and telephone numbers of each employer;
2. All past due renewal fees set forth in N.J.A.C. 13:39–1.3;
3. A reinstatement fee set forth in N.J.A.C. 13:39–1.3;
4. Any outstanding penalties imposed by the Board; and
5. Evidence of having completed all delinquent continuing education credits consistent with the requirements of N.J.A.C. 13:39–3A to a maximum of five years or 75 credits.

(b) If the license has been administratively suspended for a period of more than five years, a pharmacist applying for reinstatement shall satisfy all requirements in (a)1 through 4 above and shall pass the MJPE and the NAPLEX.

(c) A pharmacist who has had his or her license suspended pursuant to disciplinary action taken by the Board may apply to the Board for reinstatementof his or her license at the conclusion of the suspension period. A pharmacist applying for reinstatement from a disciplinary suspension shall submit:

1. A reinstatement application, including an affidavit of employment listing each job held during the period of license suspension, including the names, addresses, and telephone numbers of each employer;
2. A reinstatement fee set forth in N.J.A.C. 13:39–1.3;

3. The applicable renewal fee(s) set forth in N.J.A.C. 13:39–1.3; and

4. Evidence of having met all conditions imposed by the Board pursuant to the disciplinary and/or reinstatement order(s).

13:39–2.18 Inactive licensure

(a) A pharmacist may, upon application to the Board, choose inactive status. A pharmacist electing inactive status shall not engage in the practice of pharmacy in New Jersey for the entire biennial registration period. A licensee on inactive status may resume the practice of pharmacy in New Jersey upon application to the Board consistent with the following requirements:

1. If a licensee was practicing pharmacy in another state where he or she is licensed, and practiced for at least 1,000 hours within the two years immediately prior to the date of application for return to active status, the licensee shall remit payment of the renewal fee for the current biennial registration period set forth in N.J.A.C. 13:39–1.3;

2. If a licensee was practicing pharmacy in another state where he or she is licensed, but practiced for less than 1,000 hours within the two years immediately prior to the date of application for return to active status, the licensee shall submit evidence of having completed 30 credits of continuing education, consistent with the requirements set forth in N.J.A.C. 13:39–3A.1, within the two years immediately prior to the date of application. The licensee shall also remit the renewal fee for the current biennial registration period set forth in N.J.A.C. 13:39–1.3; and

3. If a licensee has not practiced pharmacy in another state during the inactive period, the licensee shall submit evidence of having completed 15 credits of continuing education per year, consistent with the requirements set forth in N.J.A.C. 13:39–3A to a maximum of 75 credits. At least 30 credits shall have been completed within the two years immediately prior to the date of application to return to active status. The licensee shall also remit the renewal fee for the current biennial registration period set forth in N.J.A.C. 13:39–1.3.

13:39–2.19 Steering prohibited

It shall be unlawful for a pharmacist to enter into an arrangement with a health care practitioner who is licensed to issue prescriptions for the purpose of directing or diverting patients to or from a specified pharmacy or restraining in any way a patient's freedom of choice to select a pharmacy.

13:39–2.20 Responsibilities of pharmacists

(a) All pharmacists shall be responsible for compliance with all the rules, regulations and laws governing the practice of pharmacy.

(b) Any pharmacist found to have violated the Pharmacy Act, N.J.S.A. 45:14–1 et seq., and the rules in this chapter, shall be subject to disciplinary action.

SUBCHAPTER 3. LICENSURE BY RECIPROCITY

13:39–3.1 Limitation of reciprocal licensure

(a) Reciprocal licensure of out-of-State pharmacists shall be limited to those pharmacists who have been duly licensed in mutually reciprocating states.

(b) An applicant for reciprocal licensure shall submit an application to the Board demonstrating satisfaction of the requirements set forth in N.J.A.C. 13:39–3.2.

(c) Applicants who have graduated from pharmacy schools which have not been accredited by the American Council on Pharmaceutical Education but who have been licensed by the District of Columbia, a reciprocating state or a United States territory shall be eligible for transfer of licensure if the Board is satisfied that the licensing procedures applicable to graduates of non-accredited schools in a state of licensure are equivalent to the Board's standards for licensure at the time initial licensure was obtained.

13:39–3.2 Requirements for reciprocal licensure of pharmacist currently licensed in another jurisdiction

(a) In order for a pharmacist currently licensed in another jurisdiction to obtain a license by reciprocity in this State, an applicant shall submit a completed application and the licensure fee set forth in N.J.A.C. 13:39–1.3. The completed application shall include evidence that:

1. The applicant has attained the age of 18;
2. The applicant is of good moral character and satisfies the requirements of N.J.A.C. 13:39–3.3;
3. The applicant has engaged in the practice of pharmacy for a period of at least 1,000 hours within the last two years or has met the internship requirements set forth at N.J.A.C. 13:39–8, within the one-year period immediately preceding the date of application;
4. The applicant obtained initial licensure by examination and that the license is in good standing;
5. Any other license granted to the applicant by any other state has not been suspended, revoked or otherwise restricted for any reason except the failure to renew or for the failure to obtain the required continuing education credits in any state where the applicant is currently licensed but not engaged in the practice of pharmacy; and
6. The applicant has graduated and received a professional degree from a college or school of pharmacy that has been accredited by the American Council of Pharmaceutical Education (ACPE), or has graduated from a pharmacy school that has been accredited by a program that has been deemed ACPE-equivalent by ACPE.

(b) In addition to the requirements set forth in (a) above, an applicant for licensure by reciprocity shall also satisfy all licensure transfer requirements imposed by the National Association of Boards of Pharmacy.

13:39–3.3 Proof of character

(a) An applicant for licensure by reciprocity shall submit, as part of his or her licensure application, evidence that he or she:

1. Is not presently engaged in drug or alcohol use that is likely to impair the ability to practice pharmacy with reasonable skill and safety. For purposes of this section, the term ''presently'' means at this time or any time within the previous 365 days;
2. Has not been convicted of violating any law of this State or any other state of the United States relating to controlled dangerous substances or other habit-forming drugs;
3. Has not been convicted of violating any law relating to the practice of pharmacy;
4. Has not been convicted of a crime involving moral turpitude; and

5. Has not had his or her license suspended or revoked in the last five years as a result of any disciplinary proceedings in this or any other jurisdiction which proved the applicant to be in violation of any laws, rules or regulations pertaining to the practice of pharmacy, and that the applicant is not currently under such suspension or revocation.

13:39–3.4 Proof of identity of applicant

An applicant for licensure by reciprocity shall submit a passport photograph mounted on a document to be supplied by the Board requesting certain identification information.

13:39–3.5 Alleged violations of the Pharmacy Act

If an applicant for licensure by reciprocity is being investigated for any alleged violation of the Pharmacy Act, N.J.S.A. 45:14–1 et seq., the Board in its discretion may deny the applicant a license to engage in the practice of pharmacy in this State.

13:39–3.6 Criminal history background check

An applicant for licensure by reciprocity in the State shall submit his or her name, address and fingerprints for purposes of a criminal history background check to be conducted by the State of New Jersey pursuant to N.J.S.A. 45:1–28 et seq., P.L. 2002, c.104, to determine whether criminal history record information exists which may be considered by the Board in determining whether the applicant shall be licensed in the State.

13:39–3.7 Multistate Jurisprudence Pharmacy Examination

(a) An applicant for reciprocal licensure shall pass the Multistate Jurisprudence Pharmacy Examination. A passing score of not less than 75 shall be attained. If an applicant fails the examination, he or she shall be required to repeat the examination.

(b) If the applicant for reciprocal licensure fails the examination three times, the Board may direct the applicant to take remedial courses at an accredited school or college of pharmacy prior to retaking the law examination.

SUBCHAPTER 3A. CONTINUING EDUCATION

13:39–3A.1 Continuing education credit hour requirements

(a) Each applicant for biennial license renewal shall complete a minimum of 30 credits of continuing education during the preceding biennial period, except that the Board shall not require completion of continuing education credits for an applicant's initial license renewal. At least 10 of the continuing education credits shall be obtained through didactic instruction. For purposes of this paragraph, ''didactic instruction'' means in-person instruction and may include telephonic or electronic instruction that is interactive, but shall not include videotaped instruction. For the biennial renewal period commencing May 2005 and thereafter, at least three continuing education credits shall be obtained in pharmacy law applicable to the practice of pharmacy in New Jersey.

(b) Ten credits of continuing education may be carried over into a succeeding biennial period only if such credits were earned during the last six months of the preceding biennial period and were not previously reported.

13:39–3A.2 Criteria for continuing education credit

(a) A licensee may obtain continuing education credit from the following categories:

1. Programs or courses offered by American Council of Pharmaceutical Education approved providers;
2. Programs and courses that have received prior Board approval pursuant to N.J.A.C. 13:39–3A.6;
3. Graduate course work relevant to the practice of pharmacy, taken at an accredited college or university, beyond that required for professional licensure;
4. Participation in teaching and/or research appointments;
5. Participation as a preceptor in externship programs;
6. Participation as a preceptor in internship programs; and
7. Publication of an article related to the practice of pharmacy in a peer-reviewed professional journal.

13:39–3A.3 Continuing education credit hour calculations

(a) Credit for continuing education shall be granted as follows for each biennial license period:

1. Attendance at approved programs or courses shall be granted one credit for each hour of attendance. Credit shall not be granted for programs or courses which are less than one contact hour in duration, which is defined as 50 minutes of actual attendance in a program or course of study. One half credit shall be granted for each 30 minute segment of a program or course that is more than one contact hour in duration. Completion of an entire program or course is required in order to receive any continuing education credit for the program or course.
2. Successful completion of graduate course work related to the practice of pharmacy at an accredited college or university beyond that which is required for professional licensure shall be granted three continuing education credits for each course credit awarded.
3. Teaching and research appointments related to the practice of pharmacy shall be granted three continuing education credits for each new program or course taught or subject matter researched by a licensee, to a maximum of six credits. ''New,'' in this paragraph, means a program, course or subject matter which the licensee has never taught or researched before in any educational or practice setting. A licensee who is employed as a teacher and/or as a researcher on a full-time basis shall not be eligible to obtain continuing education credit for such activities.
4. Participation as a preceptor in an externship program, upon prior approval by a college of pharmacy, shall be granted three continuing education credits per student to a maximum of six credits.
5. Participation as a preceptor in an internship program shall be granted three continuing education credits per 160 hours of work performed by the intern(s) and supervised by the licensee, to a maximum of six credits.
6. Publication of an article related to the practice of pharmacy in a peer-reviewed professional journal shall be granted three continuing education credits per article to a maximum of six credits.

(b) The Board shall not grant credit for, or approve as a component of a continuing education program, participation in the routine business portion of any meeting of a pharmaceutical organization or any presentation that is offered to sell a product or promote a business enterprise.

13:39–3A.4 Continuing education credit hour reporting procedure

(a) A licensee shall specify on his or her application for biennial license renewal the number of continuing education credits completed. Falsification of any information contained in the renewal application may result in an appearance before the Board and the assessment of penalties and/or license suspension pursuant to N.J.S.A. 45:1–21 et seq.

(b) A licensee shall maintain all documentation concerning the completion of continuing education requirements for a period of five years from the completion of the credit hours and shall submit such documentation to the Board upon request. Such documentation shall consist of:

1. For programs offered by American Council of Pharmaceutical Education approved providers, a certificate of completion from the course or program;
2. For programs and courses approved by the Board, the sponsors' written verification of attendance;
3. For teaching or research appointments in an academic setting, a statement from the chairperson of the department verifying completion of the assignment;
4. For research appointments in an industrial setting, a statement from the project coordinator verifying completion of the assignment;
5. For participation as a preceptor in an externship program, a certificate from the college of pharmacy;
6. For participation as a preceptor in an internship program, a certificate from the Board; and
7. For publications in a peer-reviewed professional journal, submission of the published article.

(c) The Board shall audit licensees on a random basis at the end of each biennial period to determine compliance with continuing education requirements.

13:39–3A.5 Waiver of continuing education requirements

(a) The Board may waive continuing education requirements on an individual basis for reasons of military service, hardship, illness or disability.

(b) A licensee seeking a waiver of continuing education requirements shall apply to the Board in writing and set forth with specificity the reasons for requesting the waiver. The licensee shall also provide the Board with such additional information as the Board may request in support of the application for waiver.

(c) A waiver of continuing education requirements granted pursuant to this section shall be effective only for the biennial period in which such waiver is granted. If the condition(s) which necessitated the waiver continues into the next biennial period, a licensee shall apply to the Board for a renewal of such waiver for the new biennial period.

13:39–3A.6 Responsibilities of continuing education sponsors

(a) A continuing education sponsor shall receive prior Board approval for a program or course if the sponsor provides, in writing on a form provided by the Board, information which demonstrates that the program or course meets the following requirements:

1. The program or course is offered in a subject matter relevant to the practice of pharmacy;
2. The program or course is at least one contact hour in length; and

3. The program or course is conducted by a qualified instructor or discussion leader who submits a curriculum vitae and who is:

   i. A pharmacist with a B.S. in Pharmacy or a Pharm.D. with at least five years of experience;

   ii. A pharmacist with a B.S. in Pharmacy or a Pharm.D. with expertise in the program or course subject area;

   iii. A pharmacist with a B.S. in Pharmacy or a Pharm.D. who is certified by a nationally recognized board or association; or

   iv. A licensed health care professional who demonstrates special expertise in the lecture subject area.

(b) A continuing education sponsor may request approval for a program or course conducted by an individual who possesses expertise in a subject area relevant to the practice of pharmacy, provided that the program or course to be conducted by that individual satisfies the requirements of (a)1 and 2 above.

(c) Applications for pre-approval of continuing education programs or courses shall be submitted by the continuing education sponsor on a form provided by the Board at least 45 days prior to the date the program or course is to be offered. Incomplete applications shall be returned to the sponsor.

(d) The Board shall approve only such continuing education programs and courses as are available and advertised on a reasonable nondiscriminatory basis to all persons licensed to practice pharmacy in the State. The Board shall maintain a list of all approved programs and courses at the Board office and shall furnish the list to licensees upon request.

(e) A continuing education sponsor shall not make substantive changes to an approved program or course, such as a change in program or course content or instructor, without prior Board approval.

(f) The continuing education sponsor shall monitor attendance at, or ensure completion of, each approved program or course and furnish to each enrollee a verification of attendance which shall include at least the following information:

1. The title, date and location of the program or course offering;

2. The name of the program or course presenter;

3. The name and certificate number of the program or course presented;

4. The number of continuing education credits awarded; and

5. The name, address, telephone number and signature of the sponsor, or if the sponsor is an association or organization, the signature of an officer or responsible party of the association or organization.

(g) The continuing education sponsor shall submit the fee set forth at N.J.A.C. 13:39–1.3(a)1xii for each submission of program or course offerings.

(h) The continuing education sponsor shall maintain a list of all attendees who completed each approved program or course for a period of five years from the date the program or course was offered.

13:39–3A.7 Monitoring of continuing education programs or courses

A Board member or a Board representative may monitor an approved program or course without prior notification to the continuing education sponsor.

SUBCHAPTER 4. PHARMACY PERMIT REQUIREMENTS

13:39–4.1 New pharmacies; eligibility and application

(a) A permit application shall be submitted to the Board by every person or corporation desiring to operate a new pharmacy. Such application shall be made on a form furnished by the Board.

(b) The permit application shall indicate the exact intended location and plan or physical arrangement of the proposed pharmacy area and shall indicate any premises contiguous to but not necessarily a part of the pharmacy.

(c) The permit application shall bear the exact trade name, if any; the corporate names, if any; the name and addresses of the owners and operators, if a sole proprietorship, partnership, limited liability partnership or limited liability company; the names and addresses of all officers and stockholders and the names and addresses of all principals duly licensed to write prescriptions if the pharmacy is not a publicly traded corporation; and the names and addresses of the officers, if a publicly traded corporation.

(d) The permit application shall include the name of the registered pharmacist-in-charge who shall be a registered pharmacist in good standing in the State of New Jersey.

(e) No person, business entity or equity holder of the business entity shall be eligible for a new permit or a renewal thereof who is not of high moral character or against whom there is pending any indictment or any alleged violation of local, State or Federal law pertaining to the practice of pharmacy or the dispensing of controlled dangerous substances or any drug under N.J.S.A. 24:21–2.

(f) A person submitting an application may be interviewed by the Board to review his or her qualifications and eligibility.

(g) Before a permit may be issued to an applicant, the Board shall inspect and approve the premises, fixtures and equipment of the new pharmacy to ensure compliance with this subchapter and all relevant statutes, regulations and ordinances.

(h) Upon approval of the permit application, the Board shall issue a permit number that will allow the applicant to place prescription legend drugs in stock.

13:39–4.2 Issuance of permits

All permits shall be issued by the Board in the name of the pharmacy or other licensed establishment for the operation of which the permit is issued.

13:39–4.3 Display of permits

A permit issued by the Board for the operation of a pharmacy or other licensed establishment shall be conspicuously displayed.

13:39–4.4 Death of owner or partner

In the case of death of an individual owner or a partner, the permit issued to the deceased owner or to the partnership is terminated and shall be returned to the Board pursuant to N.J.A.C. 13:39–4.8. If the operation of the pharmacy is to be continued, the estate or heirs of the deceased partner and/or the remaining partners shall comply with the requirements set forth at N.J.A.C. 13:39–4.5.

13:39–4.5 Change of ownership

(a) Whenever there is any change in ownership of the business entity holding a permit to operate a pharmacy, the new ownership of such entity shall apply for a new permit on a form prescribed and furnished by the Board and pay a fee pursuant to N.J.A.C. 13:39–1.3. The new owner(s) of such entity shall not operate a pharmacy under an existing permit for more than 60 days following a change in ownership. Before a permit may be issued to the new owner(s) of the business entity, the Board shall inspect and approve the fixtures, equipment and inventory of the pharmacy to ensure compliance with this subchapter and all relevant statutes, regulations and ordinances, and shall require evidence of the transfer of ownership and an inventory of controlled substances being transferred to the new owner(s).

(b) Upon a change in ownership pursuant to (a) above, the new ownership of such entity shall ensure that the prescription and profile records of the previous pharmacy are maintained pursuant to N.J.A.C. 13:39–7.6 and 7.19 after the date of acquisition.

13:39–4.6 Change of corporate officers or stockholders of a publicly traded corporation

If there is a change of registered agents or officers or a change of stock ownership involving 10 percent or more of the outstanding stock of a publicly traded corporation, the corporation shall file an affidavit with the Board within 30 days indicating the changes that have taken place and any other information requested by the Board.

13:39–4.7 Change of location; remodeling of premises

(a) Whenever a pharmacy or licensed establishment changes location, the pharmacy or licensed establishment shall apply for a new permit on a form prescribed and furnished by the Board. The pharmacy or licensed establishment shall pay a fee for the new permit pursuant to N.J.A.C. 13:39–1.3. The permit holder shall not operate a pharmacy under an existing permit for more than 60 days following a change of location. Before a permit may be issued to the permit holder for the new location, the Board shall inspect and approve the premises, fixtures, equipment and inventory of the new location to ensure compliance with this subchapter and all relevant statutes, regulations and ordinances.

(b) Prior to the remodeling of a pharmacy, pharmacy department or licensed establishment, where such remodeling entails a physical change of location or size of the prescription area within the premises or a change of the physical specifications of the licensed premises, it shall be necessary to notify the Board at least 30 days in advance on a form prescribed by the Board. The permit holder shall not operate a pharmacy under an existing permit for more than 60 days following the remodeling of a pharmacy. Within 60 days of the remodeling, the Board shall inspect and approve the premises, fixtures, equipment and inventory of the remodeled pharmacy to ensure compliance with this subchapter and all relevant statutes, regulations and ordinances.

13:39–4.8 Discontinued pharmacies

(a) Whenever a pharmacy is terminated by suspension, retirement or death of the owner, sale or other cause including insolvency, the permit holder shall remove all drug signs from both the inside and outside of the discontinued pharmacy and shall notify the Board of the location of prescription records. The permit holder shall return the permit to the Board for cancellation within 30 days of the closing. Prescription records and other information may be requested by the Board as outlined in N.J.A.C. 13:39–7.6.

(b) Whenever a pharmacy is to be discontinued, the permit holder shall immediately notify by telephone the State Board of Pharmacy, the Office of Drug Control and the Drug Enforcement Administration of the proposed closing at least 15 days beforehand, followed by a letter in writing to those agencies. All medication (both prescription legend and controlled drugs) shall remain on the licensed pharmacy premises with all licenses and registrations in effect until such medications are disposed of in the manner prescribed by the above agencies.

13:39–4.9 Availability of records upon termination of business

(a) When a pharmacy ceases operation as the result of a suspension, retirement or death of the owner, sale or other cause including insolvency, the licensee, or the one responsible for supervising the disposition of the practice, shall make every effort to notify patrons of their right to retrieve currently valid prescriptions and the location of the prescriptions and profile records for a six-month period following notice, using all of the following methods:

1. Notification in writing to the Board;

2. Publication, once weekly for two successive weeks in a newspaper whose circulation encompasses the major area of the licensee's former practice, of a notice advising patrons of the right to retrieve their prescriptions and the location of the prescriptions for a six-month period following publication; and

3. A sign placed in the pharmacy location informing the patrons of the right to retrieve their prescriptions and the location of the prescriptions.

13:39–4.10 Business hours; unauthorized closing

(a) All pharmacies shall be kept open for the transaction of business at least 40 hours per week and at least five days per week.

(b) If any permanent changes are made in the opening or closing hours of a pharmacy or other Board-licensed establishment, the Board office shall be notified in writing of these changes within 30 days.

(c) A notice shall be conspicuously displayed on the exterior of any pharmacy or other Board-licensed establishment indicating any temporary changes in the opening or closing hours of the pharmacy or establishment, or indicating a temporary closing of the pharmacy or establishment whenever such changes occur.

(d) Any temporary closing of a pharmacy or other Board-licensed establishment for more than 48 hours shall be reported to and approved by the Board. Notification to the Board shall include contingency plans for accessing patient records. Any temporary closing of more than 48 hours without prior Board approval shall result in the pharmacy being deemed a discontinued pharmacy requiring compliance with the requirements of

13:39–4.11 Replacement permit

A replacement permit may be issued by the Board upon payment of a fee pursuant to N.J.A.C. 13:39–1.3 and submission of an affidavit describing the loss or destruction of the permit originally issued, or upon return of the damaged permit.

13:39–4.12 Change of name

(a) A change in the name of a pharmacy or other Board-licensed establishment shall be made upon the submission to the Board for approval of the new name and of prescription labels bearing the new name.

(b) The Board shall issue an amended permit bearing the new name upon return of the permit bearing the previous name to the Board for cancellation and payment of the permit fee as prescribed in N.J.A.C. 13:39–1.3.

13:39–4.13 Reproduction of permits

(a) Any permit issued by the Board for the operation of a pharmacy or other board-licensed establishment may only be photocopied for State agencies and other business entities with whom the permit holder does pharmacy related business.

(b) Any reproduction of a pharmacy permit by a permit holder for any unlawful purpose shall subject a permit holder to disciplinary action pursuant to N.J.S.A. 45:1–21.

13:39–4.14 Permitting of pharmacy department

(a) If the area for which a pharmacy permit is sought is less than the total store area of the enterprise, the area subject to permit shall be known as the ''Pharmacy Department.''

(b) The holder of a permit to operate a pharmacy department and the registered pharmacist-in-charge of the department shall comply with all requirements in this chapter and shall also be subject to the following additional requirements:

1. The pharmacy department shall be constructed so as to enable the closing off and securing of the department from the main store area. The department shall be separated from the main store area by a secured barrier or partition extending from the floor or fixed counter to the ceiling of either the department or main store and attached thereto. Any entrance to the pharmacy department shall be capable of being locked and connected to a security device or other Board approved security system.

2. The registered pharmacist on duty shall be responsible for keeping the pharmacy department secure and locked and the alarm system turned on at all times when he or she is not present within the department, except as provided in N.J.A.C. 13:39–6.4, and shall be responsible for the security of the keys to the department.

3. All medications requiring supervision of a pharmacist, including dispensed medication, shall remain within the confines of the department when the pharmacist is not in the pharmacy department.

4. The hours that the department is open and the name of the registered pharmacist-in-charge shall be posted in plain view at the entrance to the department and at the public entrance to the enterprise containing the department.

5. When the enterprise in which the department is located maintains different store hours from the pharmacy department, all advertising, announcements, signs or statements indicating store hours and the presence of the pharmacy department shall clearly and distinctly indicate the hours that the department is open.

6. The pharmacy department shall have a published telephone number different from that of the establishment in which the department is located. No extensions of this phone shall be located outside the department.

7. The telephone number of the registered pharmacist-in-charge shall be available in the office of the manager of the establishment.

8. There shall be provided a secure area for the receiving of prescription drugs from suppliers. No prescription drug shall be accepted fromany supplier during the hours the pharmacy department is closed unless adequate security for the storage of department shipments has been provided.

9. If a drop-off device is utilized for prescriptions it shall be of a oneway, irretrievable design.

13:39–4.15 Permits; specialized permits

(a) The Board may issue a special permit, wherein the type of service is of a limited nature. The permit so issued, being based on special conditions of use imposed by the Board, may necessitate the waiver of certain rule requirements.

(b) Specialized permits shall pertain to pharmacies providing specific services as may be necessary and proper to efficiently meet a limited public need for pharmaceutical services. An applicant for any specialized pharmacy permit shall provide the Board with an application and a policy and procedure manual which sets forth a detailed description of the type of specialized pharmacy services to be provided within the pharmacy practice. The policy and procedure manual shall also contain detailed provisions which ensure the protection of the public welfare as determined by the Board.

13:39–4.16 Steering prohibited

It shall be unlawful for a pharmacy permit holder to enter into an arrangement with a health care practitioner who is licensed to issue prescriptions for the purpose of directing or diverting patients to or from a specified pharmacy or restraining in any way a patient's freedom of choice to select a pharmacy.

13:39–4.17 Responsibilities of permit holders

(a) All permit holders shall be responsible for compliance with all the rules, regulations and laws governing the practice of pharmacy.

(b) Any permit holder may be held liable for violations of the Pharmacy Act, N.J.S.A. 45:14–1 et seq., and the rules in this chapter and may be subject to disciplinary action.

13:39–4.18 Procedures for centralized prescription handling

(a) The four component functions of handling a prescription are intake, processing, fulfillment and dispensing.

(b) Central prescription handling entails two or more licensed pharmacies sharing responsibility for performing the four component functions of handling a prescription.

(c) The following pharmacies may engage in central prescription handling: an intake or originating pharmacy; a central processing pharmacy; a central fill pharmacy; and a dispensing pharmacy. The four component functions of handling a prescription shall be performed by the following pharmacies:

1. An intake or originating pharmacy, which is a licensed pharmacy that received the patient's or prescribing practitioner's request to fill or refill a prescription. A central processing pharmacy or a central fill pharmacy, as delineated in (c)2 and 3 below, may be considered the intake or originating pharmacy if the prescription was transmitted by the prescribing practitioner directly to the centralized pharmacy as provided in N.J.A.C. 13:39–5.8A and 5.8B or if the patient requested the refill from that pharmacy;

2. A central processing pharmacy, which is a licensed pharmacy that engages in prescription review by performing functions that may include,but are not limited to, data entry, prospective

drug review, refill authorizations, interventions, patient counseling, claims submission, claims resolution and adjudication;

3. A central fill pharmacy, which is a licensed pharmacy engaging in central prescription handling by filling and/or refilling prescriptions which includes the preparation and packaging of the medication; and

4. A dispensing pharmacy, which is a licensed pharmacy that receives the processed prescription and/or the filled or refilled prescription for dispensing to the patient or to the patient's authorized representative.

(d) Two or more of the licensed pharmacies delineated in (c) above may engage in central prescription handling provided:

1. Any or all of the pharmacies participating in central prescription handling have a contractual agreement to provide such services or have the same owner;

2. Prior to engaging in central prescription handling, all pharmacies that are parties to the central prescription handling obtain Board approval. The pharmacies shall make a single application to the Board, delineating the scope of practice of each pharmacy and the specific rules in this chapter with which each pharmacy shall comply;

3. An audit trail is maintained that records and documents the name(s) or other personal identifier(s) of the pharmacist(s) or pharmacy technician(s) and the component function(s) performed by each, at the time the functions are performed, for each step of prescription handling. The audit trail shall be maintained for not less than five years from the date the prescription is filled or refilled. The oldest four years of information shall be maintained in such a manner so as to be retrievable and readable within two weeks. The most recent one year of information shall be retrievable and readable within one business day;

4. The dispensed prescription for any product bears a permanently affixed label with at least the following information:

   i. The brand name or generic name, and if generic, the name of the manufacturer;

   ii. The strength of medication, where applicable;

   iii. The quantity dispensed;

   iv. The date upon which prescription medication is dispensed;

   v. A CDS cautionary label, where applicable and when permitted by law;

   vi. The patient name;

   vii. The prescriber name;

   viii. The prescription number;

   ix. Directions for use;

   x. The phrase ''use by'' followed by the product's use by date, if dispensed in any packaging other than the manufacturer's original packaging. For purposes of this paragraph, ''use by date'' means the earlier of one year from the date of dispensing or the expiration date on the manufacturer's container;

xi. All auxiliary labeling as recommended by the manufacturer and/or as deemed appropriate in the professional judgment of the dispensing pharmacist; and

xii. The name, address and telephone number of any or all of the following:

(1) The intake pharmacy;

(2) The central processing pharmacy;

(3) The central fill pharmacy; and/or

(4) The dispensing pharmacy;

5. The patient name, the brand or generic name of the medication, and the directions for use appear in larger type, in a different color type, or in bolded type, in comparison to the other information required to appear on the label of the dispensed container pursuant to (d)4 above;

6. The patient is provided with written information, either on the prescription label or with the prescription container, that indicates which pharmacy to contact if the patient has any questions about the prescription or the medication. The written information provided to the patient shall be in bold print, easily read, and shall include the hours a pharmacist is available and a telephone number where a pharmacist may be reached. The telephone service shall be available at no cost to the pharmacy's primary patient population;

7. All pharmacies that are to engage in central prescription handling maintain a common policies and procedures manual which designates who shall be responsible for each of the component functions of handling the prescription and for ensuring compliance with the Board rules set forth in this chapter. The policies and procedures manual shall also include maintenance of the audit trail required by (d)3 above. The policies and procedures manual shall be made available to the Board upon request;

8. All pharmacies that are to engage in central prescription handling share a common electronic file; and

9. All pharmacies that are to engage in central prescription handling are responsible for ensuring that the prescription has been properly filled.

(e) A prescription for a controlled substance may be filled or refilled by pharmacies engaging in central prescription handling when permitted by law, consistent with Federal requirements set forth at 21 C.F.R.§§ 1300 et seq.

SUBCHAPTER 5. RETAIL FACILITY REQUIREMENTS

13:39–5.1 Purpose and scope

The rules in this subchapter shall apply to all retail pharmacies and retail pharmacy departments in the State. For purposes of this subchapter, ''pharmacy'' means a retail pharmacy or a retail pharmacy department.

13:39–5.2 Pharmacy access and egress

Pharmacies shall maintain entrances which are easily and safely accessible to the general public. Access to and egress from the pharmacy shall not be such that the public must traverse or traffic through any area in which prescriptions are prepared.

13:39–5.3 Pharmacy signs

(a) Pharmacies shall post a sign on the exterior of the building or a sign which is otherwise visible from a public roadway, conspicuously identifying the existence of a pharmacy on the premises, unless prohibited by lease agreement or municipal ordinance. In such case, a copy of the lease or ordinance shall be furnished to the Board.

(b) Pharmacies shall post the name of the registered pharmacist-inchargeon the entrance to the pharmacy in such a way as to be visible to the public.

13:39–5.4 Spatial requirement of pharmacy prescription area

(a) For pharmacies in operation prior to July 1, 1963, the space devoted to the prescription area and laboratory shall not be less than 10 percent of the main floor area of the pharmacy, and in no instance shall it be less than 50 square feet. If the main floor area of such pharmacy exceeds 1,200 square feet, the 10 percent requirement does not apply and the minimum requirement for the prescription area shall not be less than 120 square feet.

(b) For all other pharmacies including pharmacies subject to the provisions of (a) above which are moving to a new location, the prescription area must occupy exclusively a minimum of 150 square feet.

13:39–5.5 Prescription counter

Pharmacies shall contain a prescription counter or counters on which to work, and the free working space shall not be less than 18 inches in width and not less than 12 total feet in length. This minimum working surface shall be kept clear at all times for the processing and/or compounding of prescriptions.

13:39–5.6 Prescription area sink

An adequate sink with hot and cold running water shall be provided in the prescription area, easily accessible to the prescription counter.

13:39–5.7 Storage and adequate stock

There shall be sufficient shelf, drawer or cabinet space within the prescription area for proper storage of prescription drugs and chemicals and the minimum equipment required pursuant to N.J.A.C. 13:39–5.8.

13:39–5.8 Minimum equipment and facilities

(a) The following minimum equipment and facilities shall be required to be in every prescription area, and this equipment shall be stored so as to be readily accessible and shall be kept in a clean condition:

1. An up-to-date, comprehensive pharmaceutical reference text(s) and suitable current reference texts encompassing the general practice of pharmacy, drug interactions, drug product composition and patient counseling. Unabridged computerized versions of these reference texts shall be acceptable;
2. Over the counter Schedule V Record Book, if Schedule V medication is sold without a prescription;
3. Permanent prescription filing device and patient profile record system;
4. Securely locked, substantially constructed storage place for Schedule II controlled substances if not dispersed;

5. Class A prescription balance with a complete set of metric weights or equivalent electronic weighing device;
6. Volumetric devices capable of measuring 0.3 ml to 500 ml;
7. A glass mortar and pestle;
8. Glass funnels;
9. Stirring rods;
10. A steel spatula and a spatula of rubber or composition;
11. Ointment tile or parchment paper;
12. Refrigerator, as required by United States Pharmacopoeia Standards, to be used only for the storage of pharmaceuticals;
13. Suitable counting trays or approved counting device;
14. Labels;
15. Auxiliary labels, including poison labels;
16. Suppository mold;
17. Two Drug Utilization Review Council Placards and the current Drug Utilization Review Council Formulary; and
18. Assorted stock of prescription containers and child safety closures or caps.

13:39–5.9 Cleanliness, orderliness and sanitation

The entire prescription area shall at all times be kept in a clean, orderly and sanitary condition.

13:39–5.10 Television in prescription area prohibited

No commercial television, other than for security measures, pharmacy training or patient counseling, may be operated in a prescription area or in any location outside of a prescription area such that its operation may be viewed from the prescription area.

13:39–5.11 Prescription balances, scales, weights and automatic counting devices

All pharmacies shall have all balances, scales, weights and automatic counting devices inspected every 12 months by the Department of Weights and Measures of the municipality or county in which the pharmacy or other Board-licensed establishment is located, and such balances, scales, weights and automatic counting devices shall be properly sealed by the applicable authority.

13:39–5.12 Restriction on storage of prescription legend drugs and controlled dangerous substances

Prescription legend drugs, devices and controlled dangerous substances shall not be stored in the pharmacy in such a manner that they can be accessible to the public.

SUBCHAPTER 6. REGISTERED PHARMACIST–IN–CHARGE; PHARMACY PERSONNEL

13:39–6.1 Purpose and scope

The rules in this subchapter shall apply to all pharmacies and pharmacy departments in the State. For purposes of this subchapter, ''pharmacy'' means a retail pharmacy or a retail pharmacy department, an institutional pharmacy or a nuclear pharmacy.

13:39–6.2 Registered pharmacist-in-charge

(a) Every pharmacy shall name a pharmacist licensed and in good standing in New Jersey as the registered pharmacist-in-charge of the pharmacy. No pharmacy shall operate without a registered pharmacist-incharge for longer than 30 days.

(b) Whenever the registered pharmacist-in-charge is absent from the pharmacy for more than 30 days, the registered pharmacist-in-charge and the permit holder shall notify the Board of the name of the registered pharmacist who shall act as the interim registered pharmacist-in-charge.

(c) A registered pharmacist shall not assume the responsibilities of a registered pharmacist-in-charge of more than one pharmacy or pharmacy department simultaneously.

(d) Whenever there is a change of a registered pharmacist-in-charge of a pharmacy or other Board-licensed establishment, an inventory of all controlled dangerous substances as defined in N.J.A.C. 8:65–10.1 through 10.5 shall be performed consistent with the requirements of N.J.A.C. 8:65–5.4 and 5.5.

(e) Whenever a registered pharmacist assumes or terminates the duties as a registered pharmacist-in-charge of a pharmacy or other Board-licensed establishment, the registered pharmacist-in-charge and the permit holder shall so advise the Board in writing within 30 days by completing a form provided by the Board.

(f) A registered pharmacist-in-charge shall be a full-time employee, employed for a minimum of 35 hours per week and shall be physically present in the pharmacy or pharmacy department for that amount of time necessary to supervise and ensure that:

1. Adequate staffing is present to fulfill the needs of the pharmacy or pharmacy department;
2. Accurate records of all prescription medication received and dispensed are maintained;
3. Policies are in place regarding accurate dispensing and labeling of prescriptions and that such policies are followed;
4. Security of the prescription area and its contents are maintained at all times, including the restriction of persons unauthorized by the pharmacist on duty from being present in the prescription area while the pharmacist is temporarily absent but within the premises and the reporting of any thefts and/or diversions of controlled substances are reported upon discovery to the Office of Drug Control and the Drug Enforcement Administration pursuant to Federal and State requirements, consistent with the requirements of N.J.A.C. 8:65–2.5(d);
5. Only pharmacists and interns or externs under immediate personal supervision provide professional consultation with patients and physicians;
6. Only pharmacists, interns or externs accept telephone prescriptions and only pharmacists, interns or externs, or pharmacy technicians consistent with the requirements of N.J.A.C. 13:39–6.6(b), accept renewal authorizations;

7. No misbranded, deteriorated, adulterated, improperly stored or outdated drugs or any drugs marked ''sample'' or with any like designation or meaning are dispensed or present in the active stock in the pharmacy;

8. The prescription area is maintained in an orderly and sanitary manner; and

9. The pharmacy and all pharmacy personnel comply with all Federal and State statutes, rules and regulations governing the practice of pharmacy.

13:39–6.3 Identification tag

All personnel working in the pharmacy shall wear an identification tag which shall include at least the person's first name and job title.

13:39–6.4 Meal breaks

(a) A sole pharmacist on duty may take a 30–minute meal break while working in a pharmacy consistent with the following requirements:

1. The pharmacist shall remain in the pharmacy or, in the case of a pharmacy department, in the pharmacy department building, and shall be accessible for emergencies or for counseling, if requested;

2. The pharmacy shall remain open during the meal break for patient related services, which include, but are not limited to, the following:

i. The receipt of new written prescriptions; and

ii. The dispensing of prescription medications which have been checked by the pharmacist; and

3. A sign shall be posted in the pharmacy stating ''Pharmacist on meal break, but available for emergencies and counseling.''

13:39–6.5 Prescription prepared or compounded by pharmacy externs, interns or pharmacy technicians

A pharmacy intern, extern or technician may prepare or compound prescriptions only under the immediate personal supervision of a registered pharmacist of this State. The registered pharmacist shall be personally responsible for the accuracy and appropriateness of the filled prescription.

13:39–6.6 Pharmacy technicians

(a) Pharmacy technicians may assist the registered pharmacist in performing the following tasks:

1. Retrieval of prescription files, patient files and profiles and other such records pertaining to the practice of pharmacy;

2. Data entry;

3. Label preparation; and

4. The counting, weighing, measuring, pouring and compounding of prescription medication or stock legend drugs and controlled substances, including the filling of an automated medication system.

(b) Pharmacy technicians may accept authorization from a patient for a prescription refill, or from a physician or his or her agent for a prescription renewal, provided that the prescription remains unchanged. For purposes of this section, ''prescription refill'' means the dispensing of medications pursuant to a prescriber's authorization provided on the original prescription.

For purposes of this section, ''prescription renewal'' means the dispensing of medications pursuant to a practitioner's authorization to fill an existing prescription that has no refills remaining.

(c) Pharmacy technicians shall not:

1. Receive new verbal prescriptions;
2. Interpret a prescription or medication order for therapeutic acceptability and appropriateness;
3. Verify dosage and directions;
4. Engage in prospective drug review;
5. Provide patient counseling;
6. Monitor prescription usage;
7. Override computer alerts without first notifying the pharmacist;
8. Transfer prescriptions from one pharmacy to another pharmacy; or
9. Violate patient confidentiality.

(d) Except as provided in (e) below, a pharmacist shall not supervise more than two pharmacy technicians at any given time. Those personnel who do computer processing of prescriptions are to be included in the 1 to 2 ratio.

(e) A pharmacy that wishes to employ a registered pharmacist to pharmacy technician ratio greater than 1:2 shall:

1. Establish written job descriptions, task protocols, and policies and procedures that pertain to the duties performed by the pharmacy technician;
2. Ensure and document that each pharmacy technician passes the National Pharmacy Technician Certification Examination and fulfills the requirements to maintain this status, or completes a program which includes a testing component and which has been approved by the Board as satisfying the criteria set forth in (f) below;
3. Ensure that each pharmacy technician is knowledgeable in the established job descriptions, task protocols, and policies and procedures in the pharmacy setting in which the technician is to perform his or her duties;
4. Ensure that the duties assigned to any pharmacy technician do not exceed the established job descriptions, task protocols, and policies and procedures, nor involve any of the prohibited tasks in (c) above.
5. Ensure that each pharmacy technician receives in-service training before the pharmacy technician assumes his or her responsibilities and maintain documentation thereof;
6. Require and maintain on site a signed patient confidentiality statement from each technician;
7. Provide immediate personal supervision as defined in N.J.A.C. 13:39–1.2; and
8. Provide the Board, upon request, with a copy of the established job descriptions, task protocols, and policies and procedures for all pharmacy technician duties.

(f) If the pharmacist to pharmacy technician ratio exceeds 1:2, the pharmacy shall maintain a policy and procedure manual with regard to pharmacy technicians which shall include the following:

1. Supervision by a pharmacist;
2. Confidentiality safeguards of patient information;
3. Minimum qualifications;
4. Documentation of in-service education and/or on-going training and demonstration of competency, specific to practice site and job function;
5. General duties and responsibilities of pharmacy technicians;
6. Retrieval of prescription files, patient files, patient profile information and other records pertaining to the practice of pharmacy;
7. All functions related to prescription processing;
8. All functions related to prescription legend drug and controlled substance ordering and inventory control;
9. Prescription refill and renewal authorization;
10. Procedures dealing with documentation and records required for controlled drug substance and prescription legend drugs;
11. Procedures dealing with medication errors, including classification of medication errors;
12. Pharmacy technician functions related to automated systems;
13. Functions that may not be performed by pharmacy technicians, including at a minimum those functions listed in (c) above; and
14. A form signed by the pharmacy technician which verifies that the manual has been reviewed by the technician.

(g) The pharmacist in charge shall review at least every two years and, if necessary, amend the policy and procedure manual. Documentation of the review shall be made available to the Board upon request.

(h) On yearly pharmacy permit renewal applications, the pharmacy shall list the name and address of all pharmacy technicians which it currently employs.

(i) When pharmacy technicians are engaged in any permitted activities, the registered pharmacist(s) shall be responsible for all the activities of the pharmacy technicians.

SUBCHAPTER 7. DRUG DISPENSING AND PRESCRIPTION RECORDS

13:39–7.1 Valid prescriptions; out-of-State prescriptions

(a) A pharmacist shall only fill a written prescription issued in New Jersey if the prescription is on a New Jersey Uniform Prescription Blank pursuant to N.J.S.A. 45:14–14.4 and N.J.A.C. 13:45A–27, except as provided in N.J.A.C. 13:39–7.10 and 7.11.

(b) A pharmacist shall only fill a prescription issued by an authorized prescriber licensed to write prescriptions in the United States or any territory of the United States. Such prescriptions orders shall be filled pursuant to New Jersey law.

(c) Prescriptions, other than those listed in (a) and (b) above, shall not be filled by a pharmacy in New Jersey.

13:39–7.2 Lack of directions on original prescription

If the prescriber fails to include on the original prescription directions to the patient for use of the medication, the registered pharmacist shall make a documented attempt to contact the prescriber to obtain such directions.

In cases where the prescriber cannot be contacted, the registered pharmacist shall indicate on the label the words ''use as directed'' or ''as ordered by the physician'' or similar words to the same effect.

13:39–7.3 Authorization for renewal of prescriptions

(a) A prescription for medication or devices which pursuant to State or Federal law may be sold, dispensed or furnished only upon prescription, shall not be renewed without specific authorization of the prescriber, and the prescription may not be refilled after one year from the date of original prescription.

1. Prescriptions marked ''PRN'' or other letters or words meaning refill as needed shall not be renewed beyond one year past the date of original prescription.

(b) When the renewals listed on the original prescription have been depleted, no additional renewals may be added to the original prescription. For additional dispensing, a new prescription must be authorized by the prescriber as provided in N.J.S.A. 45:14–14, which must be reduced to writing by the pharmacist and entered into either a manual or into the electronic data processing system as a new prescription. A new prescription shall be generated and the original prescription shall remain in the prescription file in chronological order.

13:39–7.4 Emergency dispensing

(a) In the absence of a current, valid prescription, a pharmacist may dispense an emergency supply (no more than a 72–hour quantity) of a chronic maintenance drug (except controlled dangerous substances) or device if, in his or her professional judgment, refusal would endanger the health or welfare of the patient, provided the following conditions are satisfied:

1. The pharmacist first ascertains to the best of his or her ability, by direct communication with the patient or caregiver, that such a medication or device was prescribed for that patient by order of a licensed practitioner; and

2. The pharmacist documents the communication and requires the patient or caregiver to provide suitable identification and sign a statement attesting to the need before dispensing.

13:39–7.5 Approval of FDA necessary

(a) No drug or medicine other than a compounded prescription order shall be sold or dispensed in any pharmacy within the State of New Jersey until such drug or medicine has received New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Investigational New Drug Application (INDA) or other Federal Food and Drug Administration approval, where required.

(b) The storage and dispensing of all Investigational New Drugs shall be a pharmaceutical service provided in cooperation with, and in support of the principal investigator. Under these parameters the dispensing of such drugs shall not be construed to be a violation of (a) above. A pharmacy participating in experimental research shall comply with Federal Department of Health and Human Services regulations, 45 C.F.R. Part 46, Protection of Human Subjects of Research; incorporated by reference herein, as amended and supplemented.

13:39–7.6 Record of pharmacist filling prescription

(a) A registered pharmacist who fills or compounds a prescription or who supervises the filling or compounding of a prescription by an intern, nextern, or pharmacy technician shall place his or her signature or readily identifiable initials or other personal identifier on the original prescription or in the electronic data processing system.

(b) A registered pharmacist who refills a prescription shall place his or mher signature or readily identifiable initials or other personal identifier on the reverse side of the original prescription or in the electronic data processing system. Each time a prescription is refilled, the date of the refill mand the amount dispensed shall also be recorded on the original prescription or in the electronic data processing system.

(c) Initials and/or access code number(s) of the pharmacist responsible for the filled prescription shall be entered into the system each time a prescription is filled or refilled. Computer programs which automatically generate a pharmacist's initials without requiring a direct entry by the pharmacist responsible for the filled prescription at the time of dispensing are prohibited.

(d) Appropriate documentation identifying handwritten initials with the handwritten signature and printed name of the pharmacist shall be maintained by the pharmacy for a period of six years after the last date of employment.

(e) All prescription records, including original and refilled prescription data, and the number of refills authorized by the prescriber shall be maintained for a period of not less than five years. The oldest four years of record information shall be maintained in such a manner so as to be retrievable and readable within two weeks. The most recent one year of a record information shall be immediately retrievable and readable.

13:39–7.7 Copies of prescriptions

(a) A pharmacy shall immediately comply with the patient's request for copies of prescriptions. Copies of prescriptions issued directly to the patient shall state in letters at least equal in size to those describing the medication dispensed, the underlined statement: ''COPY—FOR INFORMATION ONLY.''

(b) Presentation of a labeled prescription container or a prescription marked ''COPY—FOR INFORMATION ONLY'' shall be for information mpurposes only and shall have no legal status as a valid prescription order. The pharmacist in receipt of such copy or labeled prescription container shall contact the prescribing practitioner for a new prescription or the last mdispensing pharmacy to transfer the prescription pursuant to N.J.A.C. 13:39–7.8.

13:39–7.8 Transfer of prescriptions between pharmacies

(a) When a patient, the patient's caregiver, or a pharmacy acting on behalf of a patient or caregiver requests the transfer of a valid prescription between pharmacies, a pharmacy shall immediately comply with the patient's request.

(b) Except as provided in (c) and (d) below, a prescription may be transferred between pharmacies, consistent with this section, for one year mfrom the date the prescription was written, provided refills of the prescription are available.

(c) A prescription for a Schedule II controlled substances may not be transferred.

(d) A prescription for a Schedule III, IV or V controlled substance may be transferred between pharmacies, consistent with this section, one time only, pursuant to N.J.A.C. 8:65–7.14(h) and 7.18(d).

(e) A prescription may be transferred electronically by pharmacists between pharmacies for the purpose of refill dispensing consistent with the requirements in N.J.A.C. 13:39–7.11.

(f) A prescription may be transferred by telephone between pharmacies for the purpose of refill dispensing provided that:

1. The sending pharmacy invalidates the prescription on file as of the date the prescription is transferred and records on the back of the invalidated prescription order or in the electronic system the following:

i. That the prescription has been transferred and the date of transfer;

ii. The name of the pharmacy to which the prescription was transferred;

iii. The name or personal identifier of the pharmacist, intern or mextern to whom the prescription was transferred; and

iv. The initials or personal identifier of the pharmacist, intern, or mextern issuing the transferred prescription order;

2. The receiving pharmacy, upon receiving such prescription directly from another pharmacy, records the following:

i. The name, address and original prescription number of the pharmacy from which the prescription was transferred;

ii. The name or personal identifier of the sending pharmacist, intern or extern ;

iii. All information constituting a prescription order, as well as the following:

(1) Date of issuance of original prescription;

(2) Date of original dispensing;

(3) Original number of refills authorized on original prescription;

(4) Complete refill record from original prescription;

(5) Number of valid refills remaining; and

3. The receiving pharmacist, intern, extern or technician informs the patient or caregiver that the original prescription has been cancelled at the sending pharmacy.

13:39–7.9 Filing and storage of controlled substance prescriptions

(a) Prescriptions for all controlled substances listed in Schedule II shall be maintained in a separate prescription file.

(b) Prescriptions for all controlled substances listed in Schedules III, IV and V shall be maintained in a separate prescription file for such controlled substances only or in such form that they are readily retrievable from other prescription records of the pharmacy. Prescriptions will be deemed readily retrievable if, at the time they are initially filed, the face of the prescription is stamped in red ink in the lower right corner with the letter ‘‘C’’ no less than one-inch high and filed either in the prescription file for controlled substances listed in schedule II or in the usual consecutively numbered prescription file for non-controlled substances.

13:39–7.10 Prescriptions transmitted by facsimile

(a) A pharmacist may accept for dispensing a facsimile prescription, consistent with the requirements of this section. For purposes of this section, ''facsimile prescription'' means a prescription which is transmitted by a device which sends an exact image to the receiver.

(b) A pharmacist shall not fill a facsimile prescription transmitted by anyone other than a practitioner authorized to prescribe medications pursuant to N.J.S.A. 45:14–14, or the prescribing practitioner's authorized agent.

(c) The facsimile machine used to receive prescriptions shall be located within the pharmacy prescription area.

(d) A facsimile prescription shall contain all information required to be included on a written prescription pursuant to New Jersey State Board of Medical Examiners rule N.J.A.C. 13:35–7.2(d), except that an NJPB shall not be required for the prescription.

(e) The facsimile transmission of the prescription shall contain the following:

1. The identification number of the facsimile machine which is used to transmit the prescription;

2. The date and time of the prescription transmission;

3. The name, address, telephone number and facsimile number of the pharmacy; and

4. If an authorized agent transmits the facsimile prescription, the full name and title of the transmitting agent.

(f) A pharmacist shall seek verbal verification of a facsimile prescription from the prescribing practitioner whenever the pharmacist has reason to question the authenticity, accuracy or appropriateness of the prescription. A pharmacist may accept verbal verification regarding the authenticity or legibility of a facsimile prescription from a prescribing practitioner's authorized agent. A pharmacist shall not fill a facsimile prescription where there is a question regarding authenticity, accuracy or appropriateness if such verification is not provided.

(g) A pharmacist shall retain a printed copy of a facsimile prescription, or an electronic reproduction of the facsimile prescription that is readily retrievable and printable, for a minimum of five years pursuant to N.J.S.A. 45:14–15. The printed copy shall be of non-fading legibility.

(h) A pharmacist may fill a prescription for a Schedule II controlled substance transmitted by facsimile provided that the original signed prescription is presented to the pharmacist prior to the dispensing of the controlled substance, except as provided in (h)1, 2 and 3 below.

1. A prescription for a Schedule II narcotic substance prescribed for pain management to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The facsimile shall serve as the original written prescription and shall be maintained pursuant to the requirements of (g) above.

2. A prescription for a Schedule II substance prescribed for pain management for a resident of a long-term care facility may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The facsimile shall serve as the original written prescription and shall be maintained pursuant to the requirements of (g) above.

3. A prescription for a Schedule II narcotic substance prescribed for pain management for a patient receiving services from a hospice certified by Medicare under Title XVIII or licensed by the State may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The practitioner or the practitioner's agent shall note on the facsimile prescription that the patient is a hospice patient. The facsimile shall serve as the original written prescription and shall be maintained pursuant to the requirements of (g) above.

(i) A pharmacist may fill a prescription for a Schedule III, IV or V controlled substance transmitted by facsimile consistent with the requirements of this section. The facsimile prescription shall serve as the original written prescription.

(j) A pharmacist shall not enter into any agreement with a prescribing practitioner that requires that facsimile prescriptions be transmitted to a particular pharmacy or in any way denies a patient the right to have his or her prescription transmitted by facsimile to a pharmacy of the patient's choice.

13:39–7.11 Electronically transmitted prescriptions

(a) A pharmacist may accept for dispensing an electronic prescription, consistent with the requirements of this section. For purposes of this section, ''electronic prescription'' means a prescription which is transmitted by a computer device in a secure manner, including computer to computer and computer to facsimile transmissions.

(b) A pharmacist shall not fill an electronic prescription transmitted by anyone other than a practitioner authorized to prescribe medications pursuant to N.J.S.A. 45:14–14, or the prescribing practitioner's authorized agent. If the electronic prescription is transmitted by the practitioner's authorized agent, the transmission shall include the full name and title ofthe agent.

(c) The permitholder shall ensure that the electronic system utilized to receive prescriptions shall have adequate security and system safeguards designed to prevent and detect unauthorized access, modification or manipulation of the prescriptions.

(d) The computer or device used to receive electronically transmitted prescriptions shall be located within the pharmacy prescription area.

(e) An electronic prescription shall contain all information required to be included on a written prescription pursuant to New Jersey State Board of Medical Examiners rule N.J.A.C. 13:35–7.2(d), except that a handwritten original signature and an NJPB shall not be required for the prescription.

(f) A pharmacist shall seek verbal verification of an electronic prescription from the prescribing practitioner whenever the pharmacist has reason mto question the authenticity, accuracy or appropriateness of the prescription. A pharmacist may accept verbal verification regarding the authenticity or legibility of an electronic prescription from a prescribing practitioner's authorized agent. A pharmacist shall not fill the electronic prescription where there is a question regarding authenticity, accuracy or appropriateness if such verification is not provided.

(g) A pharmacist shall retain a printed copy of an electronic prescription,or a record of an electronic prescription that is readily retrievable and printable, for a minimum of five years pursuant to N.J.S.A. 45:14–15. The ,printed copy shall be of non-fading legibility.

(h) A pharmacist may fill a prescription for a Schedule II controlled substance transmitted electronically, provided that the original signed prescription mis presented to the pharmacist prior to the dispensing of the controlled substance. If permitted by Federal law, and in accordance with Federal requirements, an electronic prescription shall serve as the original signed prescription.

(i) A pharmacist may fill a prescription for a Schedule III, IV or V controlled substance transmitted electronically, provided that the pharmacist has obtained the original signed prescription, an oral prescription, or a facsimile prescription from the prescribing practitioner or the prescribing practitioner's authorized agent prior to the dispensing. If permitted by Federal law, and in accordance with Federal requirements, an electronic prescription shall serve as the original signed prescription.

(j) A pharmacist shall not enter into any agreement with a prescribing practitioner that requires that electronic prescriptions be transmitted to a particular pharmacy or in any way denies a patient the right to have his or her prescription transmitted electronically to a pharmacy of the patient's mchoice.

(k) Two or more permit holders may establish a common electronic filing system to maintain required dispensing information.

(*l*) Nothing in this section shall be construed to preclude the electronic mtransfer of information between pharmacies for purposes of transferring prescriptions pursuant to N.J.A.C. 13:39–7.8.

13:39–7.12 Labeling

(a) The dispensed container for any product shall bear a permanently affixed label with at least the following information:

1. The pharmacy name and address;
2. The pharmacy telephone number;
3. The brand name or generic name and if generic, the name of the manufacturer;
4. The strength of medication, where applicable;
5. The quantity dispensed;
6. The date upon which prescription medication is dispensed;
7. A CDS cautionary label, where applicable;
8. The patient name;
9. Initials of the dispensing pharmacist;
10. The prescriber name;
11. The prescription number;
12. Directions for use; and
13. The phrase ''use by'' followed by the product's use by date, if dispensed in any packaging other than the manufacturer's original packaging.
    i. For purposes of this paragraph, ''use by date'' means the earlier of one year from the date of dispensing or the expiration date on the manufacturer's container.

(b) The patient name, the brand or generic name of the medication, and the directions for use shall appear in larger type, in a different color type, or in bolded type, in comparison to the other information required to mappear on the label of the dispensed container pursuant to (a) above.

(c) In addition to the requirements set forth in (a) and (b) above, the dispensed container for any product shall bear all auxiliary labeling as mrecommended by the manufacturer.

(d) When, in the judgment of the pharmacist, directions to the patient or cautionary messages are necessary, either for clarification or to ensure proper administration, storage or use of the medication, the pharmacist may add such directions or cautionary messages to those indicated by the mprescriber on the original prescription.

13:39–7.13 Professional judgment in dispensing drugs

The pharmacist shall have the right to refuse to fill a prescription if, in his or her professional judgment, the prescription is outside the scope of practice of the prescriber; or if the pharmacist has sufficient reason to question the validity of the prescription; or to protect the health and welfare of the patient.

13:39–7.14 Advertising and sale of prescription drugs

(a) ''Advertisement'' means any attempt directly or indirectly by publication, dissemination, or circulation in print or electronic media which mdirectly or indirectly induces or attempts to induce any person or entity to mpurchase or enter into an agreement to purchase services or goods from a Board licensee.

(b) Price quotations for prescription drugs appearing in any advertisement shall stipulate the strength and quantity required to be purchased for the offered cost. Price quotations shall include the usual and customary prescription cost. All services including, but not limited to, delivery charges rendered by the pharmacy which will add additional costs to the price quoted, must be set forth in the advertisement.

(c) Any reference in any form of advertisement to the quality of a drug or its beneficial use is prohibited.

(d) Price quotations for drugs appearing in any advertisement shall stipulate the effective period of price quotation.

(e) Upon request by any consumer, the pharmacist shall give usual and customary price information for a non-third party paying customer over the telephone and shall stipulate the effective period of the price quotation.

(f) All advertisements shall be predominantly informational and shall not be misleading, confusing or false. Any advertisement demeaning the quality of professional services rendered by another licensee or permittee shall be prohibited.

13:39–7.15 Restriction on sale of Schedule V over-the-counter controlled substances

(a) It shall be considered unprofessional conduct for a pharmacist to dispense a Schedule V over-the-counter controlled substance when:

1. The pharmacist, in his or her professional judgment, knows or reasonably should know that the requested substance will be used for unauthorized or illicit consumption or distribution; or

2. The pharmacist, in his or her professional judgment, knows or reasonably should know that the person requesting the substance previously used it for unauthorized or illicit consumption or distribution.

(b) The standard of professional judgment and care that attends the sale of a Schedule V over-the-counter controlled substance shall conform to the following:

1. All pharmacists shall comply with N.J.A.C. 8:65–7.19, which requires that the sale of specified controlled substances be limited in quantity during any 48–hour period, that the purchaser be at least 18 years of age, and that the pharmacist obtain suitable identification (including proof of age where appropriate) from every purchaser not known to the pharmacist.
2. In all instances, any doubts regarding the propriety of a sale of a Schedule V substance shall be resolved against making the sale.
3. The pharmacist shall enter every sale of a Schedule V substance in the Over–the–Counter Schedule V Record Book pursuant to N.J.A.C. 8:65–7.19. The information to be recorded shall include the purchaser's first and last name, street address, city and state, the name and quantity of the Schedule V substance sold, the date of each sale, and the name or initials of the pharmacist making the sale.
4. Upon an individual's second request for a Schedule V substance within a short period of time (two to four days), the pharmacist shall determine, through direct communication with the purchaser, whether the substance is being used correctly. In that regard, the pharmacist shall ascertain how many people are using the substance and whether the condition which the substance is being used to treat is improving.
5. Upon an individual's third request for a Schedule V substance within a short period of time relative to the number of persons using it (two to four days subsequent to the second purchase), the pharmacist shall advise the purchaser of the substance's abuse potential and shall caution the purchaser to consult a physician if the condition for which the substance is being used does not improve.
6. Upon an individual's fourth request for a Schedule V substance within a short period of time (two to four days subsequent to the third purchase), the pharmacist shall determine, through direct communication with the purchaser, how many people are using the substance, whether continued use will be therapeutic, whether the purchaser is treating a condition which requires a physician's consultation, whether the purchaser is exhibiting signs of drug abuse and whether the purchaser is making similar requests of other local pharmacies.
7. If a pharmacist determines that an individual's request for a Schedule V substance within a short period of time (two to four days) subsequent to his or her fourth purchase is warranted, the pharmacist shall document in the Over–the–Counter Schedule V Record Book the justification for such sale. In addition, the pharmacist shall recommend that the purchaser consult with a physician for medical evaluation due to the substance's abuse potential as well as the potential hazard presented by the substance's continued use.
8. If any Schedule V substance is dispensed to one individual more than five times within any 12–month period, the pharmacist shall obtain oral or written confirmation from the purchaser's physician as to the continued need for the substance and shall document such confirmation in the Over–the–Counter Schedule V Record Book.

13:39–7.16 Return of prescription medication

(a) Prescription medication correctly dispensed to a patient may be accepted for return by the pharmacist but shall not be placed in stock for reuse or resale, except as provided in N.J.A.C. 13:39–9.18(a)2.

(b) Prescription medication incorrectly dispensed to a patient shall be accepted for return by the pharmacist and shall not be placed back in stock for reuse or resale.

(c) Prescription medication which has been prepared for a patient, but which has not been dispensed to the patient, may be placed back in stock for reuse or resale provided that:

1. In the professional judgment of the pharmacist, the prescription medication is eligible for re-dispensing. Eligible medications are those medications that are able to be consumed by a patient within the original time frame established for the medication's stability and expiration. Products that have a limited shelf life and/or that have not been stored consistent with manufacturers' storage requirements may not be redispensed;

2. The prescription medication shall not be placed in manufacturers' stock containers of different lot numbers and/or with different expiration dates;

3. Manufacturers' stock containers shall not be over-filled;

4. In those circumstances in which prescription medications cannot be properly returned to the original manufacturers' stock containers, the medication shall be held in the pharmacy in the labeled container in which it has been repackaged;

5. If the manufacturer or the FDA orders a recall of a drug product, the pharmacist shall assume products held in labeled containers without lot numbers are included in the recall and proceed accordingly; and

6. Medications held for re-dispensing shall be used as soon as possible. Such medications, lacking original lot numbers and expiration dates, shall not be dispensed to patients beyond six months from the date the medications were originally prepared for dispensing. Re-dispensed medications shall be marked with the same use by date as the medication which was originally prepared for dispensing.

13:39–7.17 Disposal of unwanted drugs

Unwanted drugs shall be disposed of in a manner that does not cause them to become a health hazard, and in accordance with all local, State, and Federal codes.

13:39–7.18 Outdated drugs or drugs marked "sample"

No outdated, misbranded, deteriorated, improperly stored or adulterated drugs, or any drugs marked ''sample'' or with any like designation or meaning shall be dispensed or placed or maintained in active stock for use or sale.

13:39–7.19 Patient profile record system

(a) A patient profile system must be maintained by all pharmacies for persons for whom prescriptions are dispensed. The Patient Profile Record System (PPRS) shall be devised so as to enable the immediate retrieval of information necessary to enable the dispensing pharmacist to identify previously dispensed medication at the time a prescription is presented for dispensing. One profile record may be maintained for members of a family living at the same address and possessing the same family name.

(b) The following information shall be recorded in the PPRS:

1. The family name and the first name of the person for whom the medication is intended (the patient);

2. The address and telephone number of the patient;

3. Indication of the patient's age, birth date or age group (infant, child, adult) and gender;

4. The original or refill date the medication is dispensed and the initials of the dispensing pharmacist, if said initials and such date are not recorded on the back of the original prescription or in any other Boardapproved record;

5. The number or designation identifying the prescription;

6. The prescriber's name;

7. The name, strength and quantity of the drug dispensed; and

8. Pharmacist's comments relevant to the patient's drug therapy.

(c) The pharmacist shall attempt to ascertain and shall record any allergies and idiosyncrasies of the patient and any medical conditions which may relate to drug utilization, as communicated to the pharmacist by the patient.

1. If there are no patient allergies, idiosyncrasies or medical conditions which may relate to drug utilization, the pharmacist shall so indicate on the patient profile record system.

(d) The pharmacist shall use professional judgment to review and monitor the patient profile, determine if there should be any adjustment in the original patient information and so indicate the appropriate change in the patient profile record.

(e) Upon receipt of a new or refill prescription, a pharmacist shall examine the patient's profile record either in a manual or electronic data processing system before dispensing the medication, to determine the possibility of a potentially significant drug interaction, reaction or misutilization of the prescription. Upon determining a potentially significant drug interaction, reaction or misutilization, the pharmacist shall take the appropriate action to avoid or minimize the problem, which shall, if necessary, include consultation with the patient and/or the prescriber.

1. Except as set forth in (e)5 below, before dispensing a new prescription, the pharmacist shall make reasonable efforts to counsel the patient or caregiver. Counseling may, but need not, include the following:

i. The name and description of the medication;

ii. The dosage form, dosage, route of administration, and duration of drug therapy;

iii. Special directions and precautions for preparation, administration and use by the patient;

iv. Common adverse or severe side effects or interactions and contraindications that may be encountered, including their avoidance, and the action required if they occur;

v. Techniques for self-monitoring drug therapy;

vi. Proper storage;

vii. Prescription refill information; and

viii. Action to be taken in the event of a missed dose.

2. The offer to counsel may be made by ancillary personnel. However, counseling may be performed only by the pharmacist.

3. A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such consultation. The absence of any record of a failure to accept the pharmacist's offer to counsel shall be presumed to signify that the offer was accepted and that the counseling was provided.

4. If the patient or caregiver is not physically present, the offer to counsel shall be made by telephone or in writing on a separate document accompanying the prescription. A written offer to counsel shall be in bold print, easily read, and shall include the hours a pharmacist is available and a telephone number where a pharmacist may be reached. The telephone service must be available at no cost to the pharmacy's primary patient population.

5. The requirements to counsel the patient or caregiver upon receipt of a new prescription, as set forth in (e)1 through 4 above, shall not apply to a pharmacist who dispenses any drug to an inpatient at a hospital or a long term care facility in which the resident is provided with 24 hour nursing care.

6. Upon receipt of a refill prescription, a pharmacist shall determine if a substantial time, as is appropriate for that drug in the reasonable and prudent pharmacist's professional judgment, has elapsed from the last filling. When necessary, the pharmacist shall consult with the prescriber and/or the patient to assure himself or herself that continued use is appropriate.

7. When patient profile records indicate sporadic, erratic or irrational use of medication by a patient, the pharmacist shall consult with the patient and/or the prescriber to determine if continued use is appropriate.

8. All prescription patients who patronize a pharmacy shall have a profile record as specified by this section, and the pharmacist shall inquire as to whether other prescription drugs are being concomitantl utilized in order to establish a current drug history for the patient.

9. All of the foregoing assumes the patient is willing and capable of participating in his or her own plan of care.

(f) A patient profile record shall be maintained for a period of not less than five years from the date of the last entry in the profile record. In using an electronic data processing system, the system shall have the capability of producing retrievable and readable documents of all original and refilled prescription data for a period of not less than five years, including the number of refills authorized by the prescriber. The oldest four years of record information shall be maintained in such a manner so as to be retrievable and readable within two weeks. The most recent one year of a record information shall be immediately retrievable and readable.

(g) If the pharmacy uses an electronic data processing system, an auxiliary recordkeeping system shall be established when the electronic data processing system is inoperative for any reason. When the electronic data processing system is restored to operation, the patient profile information and number of refills authorized during the time the electronic system was inoperative shall be entered into the electronic data processing system within 72 hours.

(h) If an electronic data processing system is used, the system shall provide adequate safeguards against manipulation and alteration of records and to protect confidentiality of the information contained in the data bank.

(i) The holder of the pharmacy permit shall make arrangements with the supplier of data processing services or materials to ensure that the pharmacy will continue to have adequate and complete prescription and dispensing records if the relationship with such supplier terminates for any reason.

(j) Failure to comply with this section shall subject the pharmacist to disciplinary sanctions.

SUBCHAPTER 8. PHARMACY TRAINING SITES

13:39–8.1 Definitions

The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

''Certified preceptor'' means a pharmacist registered in this State who assumes the responsibility to supervise and tutor a pharmacy intern as outlined in N.J.A.C. 13:39–8.2.

''Faculty preceptor'' means a member of the faculty at an American Council of Pharmaceutical Education approved school or college of pharmacy, at which a pharmacy extern is enrolled, who assumes the responsibility to supervise and tutor a pharmacy extern as outlined in N.J.A.C. 13:39–8.2.

''Pharmacy extern'' means any person who is in the fifth or sixth college year (or third or fourth professional year) at an American Council of Pharmaceutical Education approved school or college of pharmacy who is assigned to a training site for the purpose of acquiring accredited practical experience under the supervision of the school or college at which he or she is enrolled.

''Pharmacy intern'' means any person who has graduated from an American Council of Pharmaceutical Education approved school or college of pharmacy, or if a foreign pharmacy graduate, any person who has satisfied the requirements of N.J.A.C. 13:39–2.9, who is employed in an approved training pharmacy for the purpose of acquiring accredited practical experience and who has first registered for said purposes with the Board.

''Pharmacy internship or externship'' shall mean the program of acquiring practical experience by a pharmacy intern or extern respectively.

''Pharmacy training site'' means a site which satisfies the requirements of N.J.A.C. 13:39–8.3.

13:39–8.2 Preceptor application procedures; responsibilities

(a) A registered pharmacist who wishes to be a certified preceptor shall

apply to the Board and shall furnish evidence that he or she:

1. Has been registered and employed as a pharmacist in the area of practice in which he or she is to be engaged as a preceptor, on a full-time basis for at least two years in the State of New Jersey; and

2. Has not been convicted of a crime or offense relating adversely to the practice of pharmacy or involving moral turpitude, and has not been the subject of disciplinary action taken by a professional board resulting in the suspension, revocation or surrender of a license or the placement of significant limitations on such license.

(b) The Board shall approve a certified preceptor selected by each pharmacy intern, prior to the beginning of the internship. At no time may one certified preceptor supervise the training of more than one pharmacy intern.

(c) The certified preceptor in a pharmacy training site shall provide the Board with a detailed written report outlining the progress, aptitude and readiness to practice of any pharmacy intern under his or her supervision at the conclusion of the internship.

(d) The certified preceptor or faculty preceptor is charged with the responsibility for the following:

1. Supervising the activities of the pharmacy intern or extern and ensuring that the intern or extern will keep abreast of developments in pharmacy by reading current professional literature and journals and by attending seminars and meetings of professional and scientific organizations; and

2. Providing the pharmacy intern or extern with experience and knowledge related to the preceptor's area of practice.

13:39–8.3 Pharmacy training site requirements

(a) To serve as a training site for interns, a pharmacy shall meet the following requirements:

1. Have a satisfactory record of observance of Federal, state and municipal laws and ordinances governing the activity in which it is or has been engaged.

2. Have a total number of prescriptions or medication orders filled annually, including renewals, of at least 20,000, with no more than one pharmacy intern or extern in training for each 20,000 prescriptions filled in the pharmacy.

3. Establish and maintain as part of the service it renders, a medication recordkeeping system for its patients that is approved by the Board.

4. Have available a reference library for use by the pharmacy intern.

(b) Notwithstanding the provisions of (a) above, a pharmacy which does not dispense medications but which serves as a pharmacy training site shall not be required to satisfy the requirements of (a)2 and 3 above.

13:39–8.4 Internship and externship practical experience

(a) The minimum accredited internship and externship practical experience requirement shall be the equivalent of 1,000 hours as follows:

1. One thousand hours for completion of a structured internship conducted after graduation from an accredited college of pharmacy and consisting of no less than 24 weeks supervised by a certified preceptor. Each week of practical experience shall consist of no less than 20 hours and no more than 45 hours of actual service per week. If the intern is a foreign pharmacy graduate, he or she must have met all of the requirements of the National Association of Board of Pharmacy Foreign Pharmacy Graduate Examination Commission.

2. The certified preceptor and the pharmacy intern shall keep accurate records of the time spent by the pharmacy intern for credit toward the requirements of (a)1 above. The Board shall provide appropriate forms to be submitted to the Board for approval of postgraduate practical experience.

3. No credit shall be given for hours served as an intern prior to the Board's receipt of the written application.

(b) In lieu of the requirements set forth in (a)1 above, an applicant may obtain up to 1,000 hours practical experience by completion of a structured, college-credited externship and clinical pharmacy clerkship program of an American Council of Pharmaceutical Education accredited college of pharmacy.

(c) In cases of a structured, college-credited externship and clinical pharmacy clerkship program, where less than 1,000 hours are accepted and approved by the Board, the balance of hours to make a total of 1,000 shall be gained through completion of a structured internship, conducted after graduation

from an American Council of Pharmaceutical Education accredited college of pharmacy and supervised by a certified preceptor with each week of practical experience consisting of no less than 20 hours and no more than 45 hours of actual service per week.

(d) A college of pharmacy externship program shall provide that no less than 75 percent of the hours credited toward the practical experience requirement of the Board be gained in settings in which there is direct involvement with consumers or patients, registered pharmacists, and other licensed health care practitioners such as physicians, dentists and nurses under the supervision of a certified or faculty preceptor. Not more than 45 hours of experience shall be acquired per week.

(e) Credit for college externships or other experience programs shall not be allowed for experience gained prior to the fifth college year (or third professional year) in the college of pharmacy program.

(f) The pharmacy college shall certify that the requirements of (b) above have been met.

13:39–8.5 Change in intern status

(a) A pharmacy intern applying for registration as a pharmacist in the State of New Jersey shall notify the Board within 10 days of any change in:

1. Beginning of a term of internship;
2. Termination of an internship;
3. Number of hours of employment;
4. Scheduled hours of employment;
5. Certified preceptor; and/or
6. Employing pharmacy.

13:39–8.6 Reserved

13:39–8.7 Reserved

SUBCHAPTER 9. PHARMACEUTICAL SERVICES FOR HEALTH CARE FACILITIES

13:39–9.1 Purpose and scope

(a) The rules in this subchapter shall apply to all retail pharmacies which contract to provide pharmaceutical services for healthcare facilities and to all institutional pharmacies which provide pharmaceutical services for their own health care system.

(b) An institutional pharmacy filling prescriptions for outpatient use shall comply with all retail pharmacy requirements of this chapter.

13:39–9.2 Definitions

The following words and terms, as used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

''Drug administration'' means a procedure in which a prescribed drug is given to a patient by an authorized person in accordance with all laws and rules governing such procedures.

''Formulary'' means a continually revised compilation of pharmaceuticals available in the pharmacy for use in the facility developed by the Pharmacy and Therapeutics Committee.

''Health care facility'' means a facility or institution licensed by the Department of Health and Senior Services pursuant to N.J.S.A. 26:2H–1 et seq.

''Health care system'' means one or more health care facilities which are owned or controlled by the same legal entity.

''Institutional pharmacy'' means the area in a health care facility or a health care system licensed by the Board as a pharmacy that maintains an institutional permit. ''Institutional pharmacy'' includes any areas of the health care facility or the health care system where pharmaceuticals are stored, compounded or dispensed.

''Medication order'' means a written request for medication originated by an authorized prescriber and intended for patient use in the health care facility, and not for use of the institution's employees or their dependents or outpatients of the facility's clinics. A valid medication order contains the date ordered, the patient's name and location within the facility, the name, dose, route, and frequency of administration of the medication, and any additional instructions. Computer-generated medication orders within an institutional setting, utilizing the prescriber's electronic signature or password will meet legal requirements for a prescriber's original handwritten signature on medication orders. Computerized signatures or passwords will be accepted provided that the facility has adequate safeguards which assure the confidentiality of each electronic signature or password and which prohibit their improper or unauthorized use.

''Pharmacy and Therapeutics Committee'' means the active standing committee of the institution or health care facility which is the organizational line of communication and liaison between the medical service and pharmacists and which acts to review and promote rational drug therapy and utilization in the facility.

''Unit dose drug distribution system'' means a system of dispensing drugs to be administered to patients of the facility whereby the medications are delivered daily (or more frequently) by the pharmacy to the patient care units in amounts equal to a 24–hour supply or less and are prepared, whenever possible, in single unit use packaging.

''Unit use packaging'' means a single unit use medication provided in sealed packaging which contains the following information for each unit in the package:

1. Product name;
2. Strength and/or quantity and/or volume, where appropriate;
3. Lot number;
4. Use by date;
5. Manufacturer or repackager; and
6. If there is more than one product in the single unit, a physical description of each medication in the single unit.

13:39–9.3 Licensure of institutional pharmacies

(a) Any institutional pharmacy as defined under N.J.A.C. 13:39–9.2 shall be registered with and possess an institutional permit issued by the Board. The permit shall be conspicuously displayed in the facility's pharmacy. The institutional pharmacy is subject to and shall be conducted in accordance with all existing State and Federal rules and regulations.

(b) An institutional pharmacy that is part of a health care system may fill medication orders for health care facilities that are part of the health care system and that provide pharmaceutical services directly to the patients of the health care system.

13:39–9.4 Contract pharmaceutical services; institutional permit required

An institutional permit is required for any area within an institution serviced by an outside vendor that performs on-site pharmaceutical services as defined in N.J.A.C. 13:39–1.2.

13:39–9.5 Advisory committees

The registered pharmacist-in-charge, or designee, shall be an actively participating member on any committees of the facility that may be concerned with drugs and their utilization.

13:39–9.6 Pharmacy and Therapeutics Committee; applicability; polices and procedures

(a) In all health care facilities providing pharmaceutical services to patients, an active standing committee of the institution entitled the Pharmacy and Therapeutics Committee or other appropriate name shall be established if required pursuant to Department of Health and Senior Services rules. A Pharmacy and Therapeutics Committee shall be multidisciplinary and include a pharmacist.

(b) In all health care facilities providing pharmaceutical services to patients that are not required to maintain a Pharmacy and Therapeutics Committee pursuant to Department of Health and Senior Services rules, the pharmacist-in-charge of the provider pharmacy, in cooperation with the health care facility, shall create policies and procedures as needed to provide pharmaceutical services to the health care facility. The written policies and procedures shall be available to the Board.

13:39–9.7 Institutional pharmacy staff

The institutional pharmacy shall be staffed by sufficient, competent personnel in keeping with the size, scope and complexity of the pharmaceutical services provided consistent with the requirements of N.J.A.C. 13:39–6.2(f)1.

13:39–9.8 Control of health care pharmaceutical services; responsibilities of the registered pharmacist-in-charge of the provider pharmacy

(a) The pharmaceutical services of the health care facility shall be the responsibility of and under the control, supervision, and direction of the registered pharmacist-in-charge of the provider pharmacy.

(b) If a health care facility does not have an institutional pharmacy on its premises or chooses to utilize the services of a pharmacy outside the health care system, it may enter into an agreement with a retail pharmacy licensed by the Board. The registered pharmacist-in-charge of the retail pharmacy shall direct, control, supervise and be responsible for the pharmaceutical services provided to the facility.

(c) The registered pharmacist-in-charge of the provider pharmacy, with the cooperation of the Pharmacy and Therapeutics Committee, shall develop written policies and procedures as needed to provide pharmaceutical services to the facility. The written policies and procedures shall be available to the Board.

13:39–9.9 Pharmaceutical services

The pharmaceutical services shall be provided in accordance with accepted professional principles and standards and appropriate Federal, State and local laws. These services shall be responsive to the medication needs of the patient.

13:39–9.10 Pharmaceuticals; drug supply; investigational drugs; controlled dangerous substances

(a) The pharmacist-in-charge shall be responsible for determining the specifications for drugs and pharmaceutical preparations used in the treatment of patients of the facility as to quality, quantity and source of supply. An authorized purchasing agent and/or materials manager and/or pharmacy buyer of the facility may perform the actual procurement. In such a case, the purchase shall be supervised by the pharmacist-in-charge or his or her designee, who shall be a pharmacist.

(b) Drugs approved by the Pharmacy and Therapeutics Committee for use in the facility shall be of an amount sufficient to compound or dispense all medication orders and prescriptions which may reasonably be expected to be compounded or dispensed by the pharmacist.

(c) The institutional pharmacy shall have an adequate inventory of drugs and biologicals to assure timely initiation of routine, and disaster drug therapy. Limited quantities of drugs shall be placed under controlled conditions in locations within the facility to assure immediate access by authorized licensed health care personnel for use in an emergency situation. Written policies and procedures for the maintenance, content, control and accountability of drugs supplied and located throughout the facility shall be developed by the registered pharmacist-in-charge and approved by the Pharmacy and Therapeutics Committee.

(d) The storage and dispensing of all Investigational New Drugs shall be a pharmaceutical service provided in cooperation with, and in support of the principal investigator. Under these parameters, the dispensing of these drugs shall not be construed to be a violation of N.J.A.C. 13:39–7.5(a). A facility participating in experimental research involving residents must be in compliance with Federal Department of Health and Human Services regulations, 45 C.F.R. Part 46, Protection of Human Subjects of Research, which is incorporated by reference herein, as amended and supplemented.

(e) Investigational drugs shall be properly labeled and stored in the pharmacy until dispensed. Essential information on the investigational drug shall be maintained in the pharmacy. The investigational drug may be administered only after basic chemical, pharmaceutical and pharmacological information has been made available to all concerned and all the requirements of the Food and Drug Administration and the facility are satisfied.

(f) Controlled dangerous substances shall be purchased, received, stored, dispensed, administered, recorded and controlled in accordance with State and Federal laws and regulations. Written policies and procedures concerning control, use and accountability of controlled drugs shall be developed by the registered pharmacist-in-charge.

13:39–9.11 Drug disbursement; written orders; outpatient prescriptions

(a) The pharmacist shall review the prescriber's original order, a direct copy thereof, or a facsimile before any initial dose of medication is dispensed, except as provided for in N.J.A.C. 13:39–9.13.

(b) Drugs not specifically limited as to time or number of doses when ordered shall be controlled by the automatic stop order procedure or other methods in accordance with written policies of the facility.

(c) The Pharmacy and Therapeutics Committee shall develop a list of unapproved or unacceptable abbreviations and symbols which shall not be used in the facility. Orders involving symbols or abbreviations shall only be dispensed consistent with this list.

(d) When appropriate, the pharmacist shall make necessary entries into the patient medical record relative to drug use in accordance with health care facility policies and, where applicable, pursuant to regulations of the Departmnent of Health and Senior Services and/or Centers for Medicare and Medicaid Services

13:39–9.12 Drug disbursement; oral orders

(a) The provisions of this section shall be implemented in accordance with the policy and protocols of the Pharmacy and Therapeutics Committee.

(b) A pharmacist shall receive oral orders only from an authorized prescriber. Such orders shall be immediately recorded and signed by the person receiving the order on the medication order sheet or into the electronic data processing system.

(c) Oral orders for Schedule II controlled substances shall be permitted only in the case of a bona fide emergency situation.

(d) Oral orders shall be countersigned by the prescriber.

(e) The pharmacist may release to the patient at discharge any remaining medication in a multiple dose container (for example, inhalers, multiple dose injectable medications such as insulin, topical preparation, drops, ointments, and topical irrigation solutions), provided that the pharmacist:

1. Labels the medications for out-patient use pursuant to labeling requirements set forth in N.J.S.A. 45:14–24;

2. Counsels the patient prior to discharge from the hospital or medical facility pursuant to N.J.A.C. 13:39–7.19; and

3. Ensures that discharge orders contain the attending physician's authorizations to release the remaining doses of the prescription to the patient or guardian.

13:39–9.13 Monitoring of patient drug therapy

(a) The pharmacist shall be responsible for monitoring drug therapy of patients in the facility. This shall include, but is not limited to, maintaining and reviewing the patient medication profile prior to the dispensing of medications.

(b) In instances involving the issuance and administration of STAT orders (orders requiring immediate attention) these drugs shall be documented on the patient's medication profile immediately after dispensing.

(c) When the pharmacy is closed, these drugs shall be documented on the patient's medication profile immediately after the pharmacy is reopened.

13:39–9.14 Medication not dispensed in finished form

The pharmacist shall be responsible for providing medication in a form that requires little or no further alterations, preparation, reconstitution, dilution or labeling by other licensed personnel. The pharmacist shall provide adequate instructions for those products that are not dispensed in finished form.

13:39–9.15 Drug labeling

Labeling of medications, other than intravenous solutions, shall be in conformance with written policies and procedures controlling the drug distribution system in use within the facility and in accord with current acceptable standards of pharmaceutical practice.

13:39–9.16 Use of patient's own medication

(a) No drugs shall be administered to a patient except those provided through the pharmacy or as provided by written policies and procedures developed by the registered pharmacist-in-charge or, where applicable, the director of pharmaceutical services and approved by the Pharmacy and Therapeutics Committee.

(b) Although the use of patient's own medications may be warranted in certain situations, it should be discouraged as a general or routine practice. If a patient's previously acquired medication is to be used, a written order to this effect shall be signed and dated by the patient's physician. Such medications shall be identified by the pharmacist as to contents and dispensing origin. Also, these medications shall be documented as part of the pharmacy's patient profile record system.

13:39–9.17 Drug-dispensing devices

(a) Where the use of a drug-dispensing device is approved as an integral part of the drug distribution system by the facility, the registered pharmacist- in-charge and the Pharmacy and Therapeutics Committee, the device may be used when the pharmacist is not on duty (absent during either the day or night), provided that any absence of the pharmacist does not exceed 24 hours, or when the pharmacist is on duty, provided that proper review of the use of the drug-dispensing device can be ascertained. The supervision of any drug dispensing device so utilized shall be the responsibility of the registered pharmacist-in-charge servicing the health care facility. The drug-dispensing device data shall be checked for accuracy every 24 hours by a pharmacist and so documented.

(b) Packaging and labeling of medication for drug-dispensing devices, when done in the facility, shall be performed under the immediate personal supervision of a pharmacist in the employ of or under contract to the facility.

(c) Stocking of the drug-dispensing devices with prepackaged medications shall be performed by or under the supervision of a pharmacist.

(d) The cleanliness of the drug dispensing devices shall be maintained by a pharmacist or by a person under the supervision of a pharmacist.

(e) Controlled substances and other medications to which, in the professional judgment of the registered pharmacist-in-charge, access should be limited, shall be secured within the drug dispensing device to limit access to single medications only and shall be checked and documented by the pharmacist or his or her designee who shall be a licensed professional, every 24 hours. Other than a pharmacist, only authorized registered nurses, licensed practical nurses, physicians, authorized prescribers or designated pharmacy technicians, interns and externs shall have access to the medication in each drug-dispensing device. The activity regarding all medication, including the identity of the person accessing the medication, shall be recorded and available to the pharmacist.

(f) All medications withdrawn from a drug dispensing device require a medication order by an authorized prescriber. All such medication orders shall be checked by the pharmacist within 24 hours from the time of the original order and so noted on the pharmacy's patient medication profile.

(g) When there is no licensed pharmacy on the premises and when the drug-dispensing devices are an integral part of the approved drug distribution system of the facility, the devices shall be controlled by the registered pharmacist-in-charge who is responsible for the pharmaceutical services of the institution. Under these circumstances, the time between medication order checks shall not exceed 24 hours.

13:39–9.18 Disposal of unused medications

(a) Written policies and procedures governing unused medications shall be established and implemented by the registered pharmacist-in-charge and shall comply with the following requirements:

1. All medications where the drug source, lot or control number, or expiration or use by date are missing, shall be sent to the pharmacy for final disposition, or shall be disposed of by the health care facility according to its written protocol.

2. If a unit dose packaged medication has been stored in a medication room or secure area in the institution and the medication seal and control number are intact, the medication may be recycled and redispensed.

3. Any and all medication returned by out-patients of the facility shall not be redispensed.

4. The record of disposal of unused or nonadministered dispensed controlled dangerous substances expended or wasted either by accident or intent shall be signed and cosigned and witnessed by a licensed nurse, physician or pharmacist, or where allowed by Department of Health and Senior Services rules an administrator of the health care facility, and disposed of by the health care facility according to its written protocol and consistent with all local, State and Federal laws and regulations.

13:39–9.19 Records and reports

(a) Records of the pharmaceutical services of the provider pharmacy for the facility shall be the responsibility of the registered pharmacist-in-charge. Adequate storage for pharmacy records shall be provided. Records not currently in use need not be stored in the pharmacy, but the storage facilities shall be secure, and the records shall be readily retrievable by the pharmacy staff and authorized inspectors. These records shall be made available to persons authorized to inspect them under State and Federal statutes and regulations. Patient records shall be kept confidential.

(b) The pharmacy shall maintain a patient profile record for each patient receiving drug therapy in accordance with N.J.A.C. 13:39–7.19 and as follows:

1. The profile records for inpatients shall contain: the date of each entry; the name; sex; age or birthdate; location of the patient; the drug name, dose, route of administration and quantity dispensed; the initials of the pharmacist performing the dispensing or supervising; the reported diagnosis allergies and chronic condition(s) of the patient.

2. All notations made on the inpatients' profile records by pharmacy technicians, interns and externs shall be verified and countersigned, either manually or electronically, by the supervising pharmacist.

3. The inpatient profile record shall be filed and stored for five years following patient discharge. The oldest four years of information shall be maintained in such a manner so as to be retrievable and readable within two weeks. The most recent one year of information shall be immediately retrievable and readable.

(c) All outpatient prescriptions dispensed and outpatient profile records in the institutional pharmacy shall be signed or initialed by the dispensing pharmacist, dated, filed and kept for not less than five years from the last dispensing record date.

(d) Records for receipt, use and final disposition of controlled dangerous substances shall be maintained by the institutional pharmacy in compliance with the requirements of Federal and State controlled dangerous substances laws and regulations. Nursing administration and audit records for controlled dangerous substances shall be available for review by the pharmacy.

(e) Records of the receipt, dispensing and disposal of investigational drugs shall be maintained by the institutional pharmacy in compliance with Federal and State laws and regulations.

(f) The registered pharmacist-in-charge shall be responsible for maintaining a system by which all reported adverse drug reactions are recorded and reviewed by the Pharmacy and Therapeutics Committee, where applicable, and are submitted to all appropriate State and local agencies consistent with State and local laws and regulations.

13:39–9.20 Drug information and education

(a) The registered pharmacist-in-charge shall be responsible for maintaining drug standards, references and sources of drug information current and adequate to meet the needs of the pharmacists, physicians, nurses, other health care personnel, and patients of the facility. Reference texts shall include, but not be limited to, those required by the Board under N.J.A.C. 13:39–5.8.

(b) On each patient care unit, the pharmacist shall maintain the following:

1. A copy of the current institutional formulary;
2. A reference drug compendium which will give basic information concerning drugs approved by the Pharmacy and Therapeutics Committee; and
3. The telephone number of either the local or regional poison control center.

13:39–9.21 After hours access to the institutional pharmacy

(a) Only a pharmacist shall have access to the pharmacy stock of controlled dangerous substances in Schedules II through V.

(b) Only a pharmacist shall have access to the institutional pharmacy except that in a pharmacist's absence from an institution, a registered nurse designated by the registered pharmacist-in-charge may obtain medication from the hospital pharmacy as needed in an emergency and not available as floor stock.

(c) A designated registered nurse shall remove only those medication doses which shall be administered prior to the opening of the pharmacy. The designated registered nurse may remove the following from the pharmacy stock of drugs or automated dispensing device:

1. A drug in its original container or a drug pre-packaged by the pharmacy for use in the institution;
2. The required dose(s) of a drug from the original container for a specific patient.

(d) The registered pharmacist in charge shall obtain from the registered nurse on a suitable form a record of any drugs removed showing the following:

1. The name of the drug;
2. The dosage size;
3. The amount taken;
4. The date;

5. The patient's name and location; and

6. The signature of the nurse.

(e) The registered pharmacist in charge shall obtain with the record in

(d) above the container from which the required dose(s) was taken for drug administration purposes in order that it may be properly checked by a pharmacist.

(f) All records in (d) above shall be kept by the pharmacy for five years. The oldest four years of information shall be maintained in such a manner so as to be retrievable and readable within two weeks. The most recent one year of information shall be immediately retrievable and readable.

13:39–9.22 Pharmacy facilities; space

(a) Adequate facilities (space, lighting, equipment, temperature control and supplies) shall be provided for the control of the professional, technical and administrative functions of the institutional pharmacy as needed for the effective and efficient assurance of patient safety through proper purchasing, receipt, storage, dispensing, administration and control of drugs.

(b) The facilities shall include, but are not limited to, those requirements provided in N.J.A.C. 13:39–5.4 through 5.8.

(c) The space provided for the institutional pharmacy shall be in accord with the size of the facility and the scope and complexity of the pharmaceutical services.

13:39–9.23 Storage and security

(a) Provisions shall be made for adequate safe storage of drugs wherever they are stored in the health care facility.

1. All drugs shall be secured for safe use and protected against illicit diversion. Controlled dangerous substances in the institutional pharmacy and throughout the facility shall be stored and protected in conformance with State and Federal laws and regulations.

2. Supplies of external preparations stored in patient care areas shall be kept separate from internal medications.

3. The registered pharmacist-in-charge or, where provided for in Department of Health and Senior Services rules, the director of pharmaceutical services shall be responsible for all the medications in the facility, that is, the drugs in the pharmacy area, drugs in transit, and the drugs in the patient care areas.

4. The drugs throughout the facility shall be maintained under adequate storage conditions including proper lighting, ventilation and temperature control as required by the drug manufacturer.

(b) The pharmacist-in-charge or, where provided for in Department of Health and Senior Services rules, the director of pharmaceutical services shall establish a system of control for all drugs dispensed for use in the drug therapy of patients of the facility. Inspections shall be conducted of all medication areas located in the facility or any other service area of the facility at least once every two months to check for expiration or use by dates, misbranding, physical integrity, security and accountability of all drugs dispensed for use. These inspections shall be fully documented. Written inspection reports shall be prepared and signed by the inspecting pharmacist, except for hospitals, where they can also be prepared and signed by the pharmacy technician, intern or extern and co-

signed by his or her supervising pharmacist. The pharmacist-in-charge shall be responsible for ensuring that, prior to performing any inspections pursuant to this subsection, pharmacy technicians, interns and externs are trained and can successfully demonstrate competency. Procedures for the review of these reports shall be developed and instituted by the pharmacist-in-charge and can be incorporated into the overall quality assurance program of the health care facility.

(c) Procedures shall be established to assure the immediate and efficient removal of all outdated and recalled drugs from patient care areas and from the active stock of the pharmacy. The registered pharmacist-in-charge shall develop written policies and procedures governing the removal from the facility of outdated or recalled drugs.

13:39–9.24 Equipment

Adequate equipment shall be provided for the compounding, packaging, labeling, refrigeration, sterilization, testing and safe distribution of drugs and other functions. The equipment shall be sufficient to process drugs required by the facility.

13:39–9.25 Institutional decentralized pharmacies

(a) An institutional decentralized pharmacy or a ''satellite pharmacy'', means an area within a health care system that has been issued an institutional permit and is in a location other than the original permitted location, where the preparation or dispensing or compounding of medications is performed.

(b) Medication shall not be dispensed from a decentralized pharmacy without a pharmacist present, except that, when the decentralized pharmacy is closed, a licensed nurse may dispense medication in accordance with the written policies and procedures of the institution.

(c) Institutions operating decentralized pharmacies shall notify the Board, in writing, of the existence of, and the discontinuation of, each decentralized pharmacy location.

(d) Institutional decentralized pharmacies shall be subject to normal Board inspections.

(e) Inspections of all medications in a decentralized institutional pharmacy shall be performed consistent with the requirements of N.J.A.C. 13:39–9.23.

(f) Institutional decentralized pharmacies shall comply with all requirements in this subchapter applicable to the pharmaceutical services provided by the decentralized pharmacy, as determined by the registered pharmacistin- charge.

13:39–9.26 Valid medication orders; out-of-State medication orders

(a) Only medication orders issued by an authorized prescriber licensed to write medication orders in the United States or any territory of the United States shall be considered valid medication orders and such medication orders shall be filled pursuant to New Jersey law.

(b) Medication orders, other than those listed in (a) above, shall not be filled by a pharmacy in New Jersey.

13:39–9.27 Prescriptions and medication orders transmitted by technological devices in an institution

(a) A pharmacist may, subject to the conditions set forth in this section, accept for dispensing a prescription or a medication order transmitted by a facsimile (FAX) machine or other technological device as approved by the Board.

(b) A registered pharmacist filling prescriptions under an institutional permit for employees of the institution and their dependents and for eligible outpatients may accept for dispensing prescriptions for all substances other than Schedule II controlled dangerous substances which have been transmitted by technological device, under the following conditions only:

1. Before releasing to other than an inpatient of a health care facility, as defined in N.J.A.C. 13:39–9.2, any prescription medication for a controlled dangerous substance listed in Schedules III, IV or V, the pharmacist shall obtain and file the original signed prescription.

2. The pharmacist shall, within 24 hours, reduce to hard copy, that is, record in his or her handwriting or enter into a computer, all prescriptions received by technological device other than prescriptions for Schedules III, IV and V controlled dangerous substances and shall place the copy in the permanent prescription file records.

(c) A registered pharmacist who is authorized to fill inpatient medication orders, as defined in N.J.A.C. 13:39–9.2, in an institutional pharmacy may accept all inpatient medication orders, including orders for Schedule II substances, which have been transmitted by technological device. Medication orders for narcotic Schedule II controlled substances written for long-term care facility residents or hospice patients or for direct administration to patients by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion, which are transmitted by facsimile, shall serve as the original written medication orders, in accordance with the provisions of 21 C.F.R. 1306.11(d), (e), (f) and (g).

(d) Whenever a pharmacist has reason to question the accuracy or authenticity of a prescription or medication order transmitted by technological device, the pharmacist shall verify the transmission directly with the prescribing practitioner.

(e) It shall be deemed professional misconduct for a pharmacist to use a technological device in order to circumvent his or her responsibilities with regard to documenting, authenticating and verifying medication orders and prescriptions or in order to circumvent other standards of pharmacy practice.

(f) No licensee or permit holder registered under N.J.S.A. 45:14–1 et seq. shall under any circumstances provide a technological device to, or accept a technological device from, any practitioner licensed to write prescriptions.

(g) No licensee or permit holder shall enter into any agreement with an authorized practitioner which denies the patient the right to have his or her prescription transmitted by technological device to a pharmacy of the patient's choice.

SUBCHAPTER 10. AUTOMATED MEDICATION SYSTEMS

13:39–10.1 Purpose and scope

The rules in this subchapter establish standards applicable to all pharmacies and/or facilities that utilize automated medication systems to store, package, dispense and distribute prescriptions or medication orders.

13:39–10.2 "Automated medication system" definition

As used in this subchapter, ''Automated medication system'' means any process that performs operations or activities, other than compounding or administration, relative to the storage, packaging, dispensing and distribution of medications, and which collects, controls and maintains all transaction

information. ''Automated medication system'' does not mean an automatic counting device operated pursuant to N.J.A.C. 13:39–7.11 or a mechanical drug dispensing device operated pursuant to N.J.A.C. 13:39–9.14.

13:39–10.3 Authority to use automated medication system

(a) A pharmacy may use an automated medication system to fill prescriptions or medication orders provided that:

1. The registered pharmacist in charge or the registered pharmacist under contract with a healthcare facility responsible for the dispensing of medications, pursuant to N.J.S.A. 45:14–32, if an automated medication system is utilized at a location which does not have a pharmacy on-site, is responsible for the supervision of the operation of the system;
2. The Board has conducted an inspection of the pharmacy, including an inspection of the automated medication system;
3. The automated medication system has been tested by the pharmacy and found to dispense accurately. The pharmacy shall make the results of such testing available to the Board upon request; and
4. The pharmacy has made the automated medication system available to the Board for the purpose of inspection, whereby the Board may validate the accuracy of the system.

(b) The registered pharmacist in charge or the registered pharmacist under contract with a healthcare facility responsible for the dispensing of medications shall be responsible for the following:

1. Reviewing and approving all policies and procedures for system operation, safety, security, accuracy and access, patient confidentiality and prevention of unauthorized access and malfunction;
2. Ensuring that medications in the automated medication system are inspected, at least monthly, for expiration or use by date, misbranding and physical integrity, and ensuring that the automated medication system is inspected, at least monthly, for security and accountability;
3. Assigning, discontinuing or changing personnel access to the automated medication system;
4. Ensuring that the automated medication system is stocked accurately and an accountability record is maintained in accordance with the written policies and procedures of operation; and
5. Ensuring compliance with all applicable provisions of N.J.A.C. 13:39.

13:39–10.4 Written policies and procedures of operation

(a) When an automated medication system is used to fill prescriptions or medication orders, it shall be operated according to written policies and procedures of operation. The policies and procedures of operation shall:

1. Include a table of contents;
2. Include a description of all procedures of operation;
3. Set forth methods that shall ensure retention of each amendment, addition, deletion or other change to the policies and procedures of operation for at least two years after the change is made. Each such change shall be signed or initialed by the registered pharmacist in charge and shall include the date on which the registered pharmacist in charge approved the change;

4. Set forth methods that shall ensure that a pharmacist currently licensed in the transmitting jurisdiction reviews and approves the transmission of each original or new prescription or medication order to the automated medication system before the transmission is made;

5. Set forth methods that shall ensure that access to the records of medications and other medical information of the patients maintained by the pharmacy is limited to licensed practitioners or personnel approved to have access to the records, for the purpose of complying with N.J.A.C. 13:39–7.14(h);

6. Set forth methods that shall ensure that access to the automated medication system for stocking and retrieval of medications is limited to licensed practitioners or qualified support personnel acting under the supervision of a registered pharmacist. An accountability record which documents all transactions relative to stocking and removing medications from the automated medication system shall be maintained; and

7. Identify the circumstances under which medications may be removed from the automated medication system by a licensed practitioner for distribution to a patient without prior order review by a registered pharmacist.

(b) A pharmacy which uses an automated medication system to fill prescriptions or medication orders shall, at least annually, review its written policies and procedures of operation and revise them if necessary.

(c) A copy of the written policies and procedures of operation adopted pursuant to this section shall be retained at the pharmacy and at the healthcare facility where the automated medication system is utilized. Upon request, the pharmacy shall provide to the Board a copy of the written policies and procedures of operation for inspection and review.

13:39–10.5 Personnel training requirements

The registered pharmacist in charge shall be responsible for ensuring that, prior to performing any services in connection with an automated medication system, all licensed practitioners and pharmacy technicians, interns and externs are trained in the pharmacy's standard operating procedures with regard to automated medication systems as set forth in the written policies and procedures of operation maintained pursuant to N.J.A.C. 13:39–10.4.

13:39–10.6 Written program for quality assurance

(a) A pharmacy which uses an automated medication system to fill prescriptions or medication orders shall operate according to a written program for quality assurance of the automated medication system which:

1. Requires continuous monitoring of the automated medication system;

2. Establishes mechanisms and procedures to test the accuracy of the automated medication system at least every six months and whenever any upgrade or change is made to the system;

3. Establishes a protocol for measuring the effectiveness of the automated medication system;

4. Requires the pharmacy to report to the Board each recurring error of the automated medication system. A ''recurring error,'' for purposes of this section, means any specific type of inaccuracy within the automated medication system that occurs more than twice within a 14 day period; and

5. Requires the pharmacy to maintain all documentation relating to the written program for quality assurance for at least two years.

13:39–10.7 Written plan for recovery

(a) A pharmacy which uses an automated medication system to fill prescriptions or medication orders shall maintain a written plan for recovery from a disaster which interrupts the ability of the pharmacy to provide services. The written plan for recovery shall include:

1. Planning and preparation for a disaster;
2. Procedures for response to a disaster;
3. Procedures for the maintenance and testing of the written plan for recovery; and
4. A procedure to notify the Board, each organization which has contracted with the pharmacy, each patient of the pharmacy, and other appropriate agencies, of a disaster and the date on which the pharmacy expects to recommence the provision of service.

13:39–10.8 Written program for preventative maintenance of automated medication system

A pharmacy which uses an automated medication system to fill prescriptions or medication orders shall maintain a written program for preventative maintenance of the system.

SUBCHAPTER 11. COMPOUNDING IN RETAIL AND INSTITUTIONAL PHARMACIES FOR STERILE AND/OR NON–STERILE PREPARATIONS

13:39–11.1 Purpose and scope

This subchapter shall apply to all retail and institutional pharmacies which compound and dispense sterile and/or non-sterile preparations.

13:39–11.2 Definitions

The following words and terms, when used in this subchapter, shall have the following meanings:

''ISO class 5 air quality conditions'' means conditions in which the air particle count is no greater than a total of 3,520 particles of 0.5 micrometers and larger per cubic meter of air (100 particles per cubic foot).

''ISO class 6 air quality conditions'' means conditions in which the air particle count is no greater than a total of 35,200 particles of 0.5 micrometers and larger per cubic meter of air (1,000 particles per cubic foot).

''ISO class 7 air quality conditions'' means conditions in which the air particle count is no greater than a total of 352,000 particles of 0.5 micrometers and larger per cubic meter of air (10,000 particles per cubic foot).

13:39–11.3 Sterile and non-sterile preparation services; environment

(a) A sterile preparation service is one specializing in the compounding and dispensing of sterile preparations upon receipt of a valid prescription or medication order. Such compounding shall take place in the confines of a controlled environment as required by N.J.A.C. 13:39–11.16; or when circumstances permit as set forth in N.J.A.C. 13:39–11.11(c), in a laminar hood, as provided by N.J.A.C. 13:39–11.22, or in a glove box, as provided by N.J.A.C. 13:39–11.23.

(b) Compounding of non-sterile preparations shall take place in a compounding environment designated specifically for that purpose.

13:39–11.4 General requirement for compounded sterile preparations; pre-approval

An applicant or permitholder who wishes to compound sterile preparations shall notify the Board at least 60 days prior to commencement and shall receive approval from the Board before commencing compounding of sterile preparations.

13:39–11.5 Pharmacist in charge and permitholders' responsibilities

(a) The pharmacist-in-charge shall supervise all sterile and/or non-sterile compounding. For purposes of supervising sterile compounding, the pharmacist- in-charge shall be trained in aseptic manipulation skills.

(b) The pharmacist in charge shall have the responsibility, in that section of the pharmacy where sterile and/or non-sterile preparations are compounded, for, at a minimum, the following:

1. Compounding of all preparations within the pharmacy or pharmacy satellite, including compounding of individual medication orders or prescriptions, the formulation of products in response to special drug needs and batch compounding;
2. Storage of all materials pertinent to the compounding of preparations, including drugs, chemicals and biologicals, and the establishment of specifications for procurement of the materials in accordance with State and Federal laws and regulations;
3. Ensuring that all packaging and labeling of all drugs compounded with the pharmacy are performed under the immediate personal supervision of a pharmacist;
4. Recording all transactions of the pharmacy as may be applicable to State, Federal and local laws and rules, as may be necessary to maintain accurate control over, and accountability for, all pharmaceutical materials;
5. Ensuring that preparation and compounding of sterile preparations is performed only by licensed pharmacists who have been trained in aseptic manipulation skills, or by pharmacy technicians, interns or externs who have been trained in aseptic manipulation skills working under the immediate personal supervision of a licensed pharmacist trained in aseptic manipulation skills;
6. Ensuring that preparation and compounding of non-sterile preparations is performed only by licensed pharmacists or by pharmacy technicians, intern or externs working under the immediate personal supervision of a licensed pharmacist; and
7. Establishing procedures for maintaining the integrity and manufacturer's control identity of packaged material. The packaging records shall be initialed by the supervising pharmacist.

13:39–11.6 Pharmacy technicians, interns and externs; required supervision

(a) Dispensing pharmacists shall provide immediate personal supervision to pharmacy technicians, interns or externs who are performing delegated sterile and non-sterile preparation compounding. The ratio of dispensing pharmacists to pharmacy technicians shall not exceed 1:2 at any given time unless all of the requirements of N.J.A.C. 13:39–6.6(d) and (e) are met.

1. Supervision shall include, but is not limited to, the checking of each ingredient used, the quantity of each ingredient whether weighed, measured or counted, and the finished label.

(b) The dispensing pharmacist may delegate to pharmacy technicians, interns or externs only the following tasks: recording of the prescription, selection of the drugs, container and diluent, typing of labels and compounding of preparations. The dispensing pharmacist shall ensure that each task has been performed correctly in the dispensing process.

13:39–11.7 Training requirements for compounding sterile preparations

(a) The pharmacist in charge and all personnel involved in compounding sterile preparations shall have practical or academic training in sterile preparation compounding, clean room technology, laminar flow technology, and quality assurance techniques. Such training shall be documented for each person before that individual begins to compound sterile preparations and annually thereafter. That documentation shall be maintained by the permitholder for five years and made available to the Board upon request.

(b) The pharmacist in charge shall be responsible for ensuring that, prior to compounding sterile preparations, all personnel are trained and can successfully demonstrate:

1. Comprehensive knowledge of the pharmacy's standard operating procedures with regard to compounding sterile preparations as set forth in the policy and procedure manual required to be maintained pursuant to N.J.A.C. 13:39–11.13;
2. Familiarity with the necessary compounding techniques; and
3. Appropriate aseptic technique, which shall be proven by means of a test batch of culture media, media fill or the equivalent.

(c) At least annually, the pharmacist in charge shall be responsible for testing the aseptic technique of all personnel involved in compounding sterile preparations by means of a test batch of culture media, media fill or the equivalent. Test results shall be maintained for five years, and shall be made available for the Board's inspection upon request. Individuals who fail to demonstrate acceptable aseptic technique shall be prohibited from engaging in sterile preparation compounding until demonstrating acceptable technique by means of a test batch of culture media, media fill or the equivalent.

13:39–11.8 Batch preparation

Pharmacists and pharmacy technicians, interns and externs may compound sterile and non-sterile preparations consistent with the provisions of N.J.A.C. 13:39–11.6 in a quantity that is supported by prior valid prescription or medication orders before receiving a valid written prescription or medication order, provided the pharmacist can document a history of valid prescriptions subsequently received shortly thereafter or medication orders that have been generated solely within an established professional prescriber- patient-pharmacist relationship, and provided they maintain the prescription on file for all such products dispensed at the pharmacy as required by state law. The pharmacist shall document the batch preparation process in accordance with N.J.A.C. 13:39–11.9(d).

13:39–11.9 Documentation

(a) Consistent with the provisions of N.J.A.C. 13:39–11.5, the dispensing pharmacist shall ensure that compounded preparations have been properly prepared, labeled, controlled, stored, dispensed and distributed in accordance with the provisions of this subchapter.

(b) The pharmacist in charge shall be responsible for ensuring that policies and procedures exist so that all aspects of the dispensing process set out in (d) below are documented and that the pharmacist responsible for each preparation can be identified.

(c) The dispensing pharmacist shall assure that appropriate documentation is maintained to track completion of each of the steps of the compounding process set out in (d) below.

(d) Compounding steps which shall be documented are as follows:

1. Receipt of prescription or medication order;
2. Recording of prescription or medication order in the patient record profile system, pursuant to N.J.A.C. 13:39–11.15;
3. Correct selection of the drugs, container, and diluent prior to their being compounded;
4. Verification that all pharmacy sterile preparation compounding is performed within a ISO class 5 laminar air flow hood or ISO class 5 clean room and that proper aseptic procedures are being used at all times to prevent bacterial contamination of this product;
5. Verification that ingredients comply with the prescription or medication order;
6. Verification that the prescription or medication order label complies with the requirements of N.J.A.C. 13:39–11.10; and
7. Verification that the prescription or medication order is complete and ready to be dispensed, including any necessary ancillary supplies.

(e) The completed documentation shall be maintained for not less than five years from the date of the last entry in the record. The oldest four years of record information shall be maintained in such a manner so as to be retrievable and readable within two weeks. The most recent one year of a record shall be immediately retrievable and readable within 24 hours.

13:39–11.10 Information required to appear on prescription label

(a) The dispensed container for any compounded preparation shall bear a permanently affixed label with at least the following information:

1. The date and, for sterile preparations, the time prepared;
2. In the retail pharmacy only, the name of the prescriber;
3. The name of the patient;
4. Directions for use;
5. The name and quantity of all active ingredients;
6. The name or identifying code of the pharmacist who checked or prepared the compounded preparation;
7. The name, address, and telephone number of the pharmacy;
8. The use by date and, for sterile preparations, the use by time (If no time is stated, it is presumed to be 11:59 P.M. of the stated use by date).
9. Any ancillary and cautionary instructions as needed;
10. As pertinent, a warning consistent with applicable Federal and State law that cytotoxic products are biohazardous; and
11. As pertinent, the requirements for proper storage.

13:39–11.11 Use by date of sterile preparation

(a) The use by date of a sterile compounded preparation shall be 24 hours or as otherwise stated by the manufacturer or current literature at the time of preparation, but shall not exceed 30 days after preparation.

(b) Any use by date that extends beyond 24 hours or the manufacturer's expiration date shall be substantiated by documentation satisfactory to the Board. Satisfactory documentation shall include, but not be limited to:

1. Manufacturer's criteria on extending beyond use dates;
2. Appropriate literature; and
3. Direct testing.

(c) In an institutional pharmacy, any sterile compounded preparation which is prepared under the pharmacy's control in a ISO class 5 laminar air flow hood which is not in a clean room and which meets the requirements of N.J.A.C. 13:39–11.22, shall be labeled to indicate that administration to a patient shall be initiated and completed within 28 hours of the beginning of the preparation time. If such a compounded preparation is prepared by closed-system aseptic transfer of a single, sterile, nonpyrogenic, finished medication obtained from licensed manufacturers into sterile final containers (for example, syringes, minibags, portable infusion-device cassettes), then the compounded preparation shall be labeled to indicate that administration to a patient shall be completed within the time recommended by the manufacturer but not exceeding 30 days after preparation. A closed system aseptic transfer is one which does not permit exposure of the pharmaceutical components to the environment, and shall be prepared in a ISO class 5 laminar air flow hood.

13:39–11.12 Handling, packaging and delivery

(a) The pharmacy shall be responsible for the proper handling and packaging of compounded preparations for delivery from the pharmacy to the patient in order to assure and maintain integrity, efficacy, stability, and, where applicable, sterility, of these preparations. The pharmacist in charge shall ensure that:

1. A reasonable effort is made to provide tamper-evident packing;
2. Retail delivery is made from the pharmacy to the patient within a reasonable time; and
3. Proper in-transit storage is provided consistent with product labeling.

13:39–11.13 Policy and procedure manual for compounded sterile preparations

(a) The pharmacist in charge shall maintain a policy and procedure manual which shall set forth in detail the licensee's standard operating procedures with regard to compounded sterile preparations.

(b) The policy and procedure manual shall include policies and procedures governing the following:

1. A risk-management program (including, but not limited to, incident report procedures, an adverse drug reaction system, and a product contamination system);
2. Security measures ensuring that the premises where compounded sterile drugs are present are secured, so as to prevent access by unauthorized personnel;
3. Equipment;

i. Procedures for use; and

ii. Documentation of appropriate certifications;

4. Sanitation standards and procedures;

5. Reference materials as set out in N.J.A.C. 13:39–5.8 and 11.24;

6. Information concerning drug:

i. Preparation;

ii. Storage and handling;

iii. Dispensing;

iv. Labeling;

v. Delivery; and

vi. Destruction, recalls and returns;

7. Patient recordkeeping as set forth in N.J.A.C. 13:39–11.15;

8. Handling, dispensing and documentation of investigational new drugs;

9. A quality assurance program as set forth in N.J.A.C. 13:39–11.14;

10. Verification of training and competency guidelines as set forth in N.J.A.C. 13:39–11.7;

11. Compounding process validation;

12. Documentation as set forth in N.J.A.C. 13:39–11.9;

13. Description of appropriate garb;

14. Conduct guidelines for personnel in the controlled areas;

15. Personnel responsibilities;

16. Patient education (retail patients);

17. Protocol and procedures to maintain the integrity of the interior work area of the laminar air flow hoods; and

18. Written procedures in compliance with the Occupational Safety and Health Administration standards for handling small and large spills of antineoplastic agents and other hazardous substances.

(c) The pharmacist in charge shall review at least every two years and, if necessary, amend the policy and procedure manual as needed. Documentation of the review shall be made available to the Board upon request.

13:39–11.14 Quality assurance program for compounded sterile preparations

(a) This section shall apply both to commercially available sterile drug products that are dispensed to patients without compounding or other manipulation, and to sterile preparations which, prior to dispensing, have been in any way repackaged, reconstituted, diluted, admixed, blended, or otherwise manipulated (collectively referred to as ‘‘compounded’’).

(b) The dispensing pharmacist shall ensure that the compounded sterile preparation retains its quality attributes within acceptable limits through a written quality assurance program. The quality assurance program shall require at least that:

1. A reasonable effort shall be made by the dispensing pharmacist to assure that compounded sterile preparations shall be kept under appropriate controlled conditions at the location of use by providing adequate labeling and verbal or written instructions regarding proper storage and administration as set forth by the product manufacturer, with each compounded sterile preparation dispensed;

2. The quality assurance program encompasses all phases of sterile compounding, including preparation, distribution, storage, administration, and directions for use for each type of product dispensed;

3. All compounding processes representative of all types of manipulations, products and batches must be sterile tested and validated at least every 12 months.

4. Air and surface sampling for microbial organisms in ISO class 5 laminar air flow hoods and ISO class 6 clean rooms is done twice annually and at any time when microbial contamination is suspected pursuant to United States Pharmacopoeia/National Formulary guidelines;

5. Laminar air flow hoods shall be certified every six months, and every time they are moved, by an independent certification company;

6. The ISO class 6 clean room and ISO class 7 anteroom shall be certified every six months by an independent certification company; and

7. All unused drugs and materials used in the compounding of sterile preparations, including antineoplastic agents, are disposed of properly in accordance with accepted professional standards and applicable laws, including the Medical Waste Act (N.J.S.A. 13:1E–48.1 et seq., P.L. 1989, c.34).

13:39–11.15 Patient profile records for compounded sterile preparations

(a) The pharmacist in charge shall ensure that a patient profile record is maintained and monitored for each patient. The patient profile record shall include, but is not limited to, the following:

1. Available medical information consistent with N.J.A.C. 13:39–7.19; and

2. All medication orders for institutional patients.

(b) The pharmacist in charge shall ensure that a reasonable, documented attempt is made to include in the record over-the-counter and home remedies used by noninstitutional patients.

(c) The pharmacist in charge shall ensure that initial and ongoing multidisciplinary clinical monitoring and comprehensive care plans are maintained and readily available.

13:39–11.16 Controlled environment for compounded sterile preparations: use, access, location; temperature

(a) The pharmacy shall have a designated area for sterile preparation compounding, known as the ‘‘controlled environment,’’ consisting of a clean room and an anteroom unless the pharmacy meets the requirements of N.J.A.C. 13:39–11.22 or 11.23.

(b) A controlled environment shall be:

1. Accessible only to designated personnel;
2. Used only for the compounding of sterile preparations, or such other tasks that require a controlled environment;
3. Structurally isolated from other areas within the pharmacy by means of restricted entry or access; and
4. Air conditioned to maintain a temperature of 59 to 77 degrees Fahrenheit.

13:39–11.17 Controlled environment for compounded sterile preparations: construction

(a) The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the controlled environment shall be smooth, impervious, free from cracks and crevices, and nonshedding, thereby minimizing spaces in which microorganisms and other contaminants may accumulate.

(b) All surfaces shall be resistant to damage from sanitizing agents.

(c) Junctures where ceilings meet wall shall be covered, caulked or sealed to avoid cracks and crevices where dirt can accumulate.

(d) Ceilings which consist of inlaid panels shall be impregnated with a polymer to render them impervious and hydrophobic and shall either be caulked or weighted and clipped.

(e) Solid walls shall consist either of panels locked together and sealed, or of epoxy-coated gypsum board.

(f) Floors shall have vinyl floor covering and shall be seamless or have heat-welded seams and coving to the sidewall.

(g) There shall be no dust-collection overhangs (such as ceiling utility pipes) or ledges (such as window sills). All sprinkler heads shall be flush with the ceiling.

(h) Ceiling lighting fixtures shall have exterior lens surfaces which are smooth, mounted flush, and air tight.

(i) All areas in ceilings and walls where the surface has been penetrated shall be sealed.

(j) Any clean room construction other than that specified in (a) through

(i) above (for example, softwall, prefabricated, modular, portable clean rooms) shall be approved by the Board prior to installation and use.

13:39–11.18 Controlled environment for compounded sterile preparations: stocking, maintenance and supplies

(a) The controlled environment shall contain only the following:

1. Items such as furniture, equipment, supplies, and other goods which are required for the tasks to be performed there;
2. Items which are nonpermeable, nonshedding, and resistant to disinfectants; and
3. Items which have been cleaned and sanitized immediately prior to their being placed in the clean room.

(b) Whenever possible, equipment and other items used in the controlled environment should not be taken from these rooms except for calibration, servicing, or other activity associated with the proper maintenance of the item.

(c) The controlled environment shall be kept clean and arranged in an orderly fashion. All required equipment shall be maintained in good operating condition.

(d) The controlled environment shall not be used for bulk storage, warehousing, or clerical and secretarial functions.

(e) The controlled environment area shall contain the following supplies:

1. Gloves, masks, gowns, and other personal protective equipment;

2. Needles and syringes of various sizes;

3. Disinfectant cleaning agents;

4. Clean towels;

5. Hand-washing materials, including antimicrobial skin cleaner; and

6. Any and all supplies necessary for the aseptic compounding of sterile preparations.

13:39–11.19 Controlled environment for compounded sterile preparations: clean room

(a) The clean room shall contain no sinks or floor drains.

(b) Work surfaces shall be constructed of smooth, impervious materials, such as stainless steel or molded plastic, so that the work surfaces may be readily cleaned and sanitized.

(c) The clean room shall be a minimum of 100 square feet in size and shall be compatible with the volume of compounding being conducted.

(d) Appropriate environmental control devices capable of maintaining ISO class 6 air-quality conditions during normal activity shall be in place.

(e) The clean room shall contain the following equipment:

1. An ISO class 5 or better laminar airflow hood or a suitable ISO class 5 or better HEPA filter system;

2. Waste containers in compliance with Occupational Safety and Health Administration (OSHA) standards for used needles and syringes, and for chemotherapy waste; and

3. Ancillary supplies required for proper compounding.

13:39–11.20 Controlled environment for compounded sterile preparations: anteroom

(a) The anteroom shall have an air quality of ISO class 7 or better.

(b) The anteroom shall contain the following equipment:

1. A sink with hot and cold running water;

2. Waste containers for all personal protective equipment;

3. An eyewash station; and

4. A hazardous waste spill kit.

(c) A refrigerator, as required by United States Pharmacopoeia Standards, shall be reasonably accessible to the anteroom to ensure the integrity of the compounded sterile preparations, but shall not be located within the controlled environment.

13:39–11.21 Vertical air laminar flow hoods for compounded sterile preparations

(a) Pharmacies shall compound antineoplastic agents and other hazardous substances in an ISO class 5 vertical air laminar flow hood.

(b) Personnel who compound and dispense antineoplastic agents and other hazardous substances shall adhere to OSHA Work Practice Guidelines, as set forth in CPL 2–2.20B CH–4, Chapter 21, incorporated herein by reference, as amended and supplemented.

13:39–11.22 Laminar air flow hoods not in a clean room for compounded sterile preparations

Institutional pharmacy ISO class 5 laminar air flow hoods not located in a clean room may only be located in an area which is maintained under sanitary conditions and traveled by persons engaging in the compounding of sterile preparations. Such hoods shall be certified by an independent certification company prior to use when first installed or after being moved and at six-month intervals.

13:39–11.23 Controlled environment for compounded sterile preparations: self-contained sterile glove boxes

Self-contained ISO class 5 glove boxes, barrier isolation technology or the equivalent not located in a clean room may only be located in an area which is maintained under sanitary conditions and traveled by persons engaging in the compounding of sterile preparations. Such boxes shall be certified by an independent certification company prior to use when first installed or after being moved and at six-month intervals.

13:39–11.24 Library references

In addition to the minimum reference library mandated in N.J.A.C. 13:39–5.8, each pharmacy engaged in compounding shall contain recognized references pertinent to specialized compounding preparations.

13:39–11.25 Disposal of drugs and materials

All unused drugs and materials used in the compounding of preparations, including antineoplastic agents, shall be disposed of properly in accordance with accepted professional standards and applicable laws, including the Medical Waste Act (N.J.S.A. 13:1E–48.1 et seq., P.L. 1989, c.34), so as not to endanger the public health.

13:39–11.26 Security

The compounding area and its contents and other areas where compounded preparations are present shall be secured, so as to prevent access by unauthorized personnel.

13:39–11.27 Reserved

SUBCHAPTER 12. NUCLEAR PHARMACIES

13:39–12.1 Definitions

The following words and terms when used in this subchapter shall have the following meanings, unless the context clearly indicates otherwise.

''Authentication of product history'' includes, but is not limited to, identifying the purchase source, the ultimate use or disposition and any intermediate handling of any components of a radiopharmaceutical.

''Authorized practitioner'' means a practitioner duly authorized by applicable Federal and State law to possess, use and administer radiopharmaceuticals.

''Designated agent'' means an individual under the direct supervision of a practitioner authorized to communicate the practitioner's instructions to the nuclear pharmacy.

''Immediate personal supervision'' means that the registered pharmacist is physically present in the compounding/dispensing area when interns, externs and pharmacy technicians are performing delegated duties, and the pharmacist conducts any necessary in-process checks and the final check in preparation and compounding of medications, including the checking of each ingredient used, the quantity of each ingredient whether weighed, measured or counted, and the finished label.

''Internal test assessment'' includes, but is not limited to, conducting those tests necessary to insure the integrity of the test.

''Radiopharmaceutical'' means any substance defined as a drug in Section 201(g)(1) of the Federal Food, Drug and Cosmetic Act or in the FDA's Nuclear Pharmacy Guidelines and which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any such drug which is intended to be made radioactive. This definition includes nuclide generators which are intended to be used in the preparation of any such substance but does not include drugs such as carbon-containing compounds or potassium-containing compounds or potassium-mcontaining salts which contain trace quantities of naturally occurring radionuclides.

''Radiopharmaceutical quality assurance'' includes, but is not limited to, the performance of appropriate chemical, biological and physical tests on radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals, including internal test assessment, authentication of product history and the keeping of proper records.

''Radiopharmaceutical service'' includes, but is not limited to, the compounding, dispensing, labeling and delivery of radiopharmaceuticals; the participation in radiopharmaceutical utilization reviews; the proper and safe storage and distribution of radiopharmaceuticals; the maintenance of radiopharmaceutical quality assurance; and the offering of those acts, services, operations or transactions necessary in the conduct, operation, management and control of a nuclear pharmacy.

13:39–12.2 General requirements for pharmacies providing radiopharmaceutical service

(a) The application for a specialized retail permit to operate a pharmacy providing radiopharmaceutical services shall only be issued to a site employing a qualified nuclear pharmacist. All personnel performing tasks in the preparing and distribution of drugs shall be under the immediate personal supervision of the nuclear pharmacist who shall be responsible for all nuclear operations of the licensed area and shall be in personal attendance at all times when the nuclear pharmacy is open for business.

(b) Nuclear pharmacies shall have adequate space, commensurate with the scope of services required and provided, meeting minimal United States Nuclear Regulatory Commission or its successor's requirements and the requirements established by the State of New Jersey Bureau of Radiation Protection. The nuclear pharmacy shall be separate from the pharmacy areas for non-radioactive drugs and shall be inaccessible to all unauthorized personnel. All pharmacies handling

radiopharmaceuticals shall be provided with a radioactive storage and decay area. A nuclear pharmacy dispensing radioactive drugs may be exempted from the general space requirements for pharmacies.

(c) The process used for handling radioactive materials by any license holder must involve appropriate procedures for the purchase, receipt, storage, manipulation, compounding, distribution, and disposal of radioactive materials. In order to ensure the public health, safety, and welfare, a nuclear pharmacy shall first meet the following general requirements:

1. The environment where the handling of radioactive materials takes place shall be properly ventilated so that radioactive materials cannot be airborne from that environment to other non-occupationally unrestricted areas;
2. The environment shall be properly located so that the receipt and dispersal of radioactive materials does not result in inadvertent and undesired contamination of other non-occupationally labeled areas; and
3. The area shall be designed in such a manner that radioactive materials can be contained in given areas to ensure adequate safety and protection to personnel working in or near them and to insure proper operation of the corresponding assay equipment.

(d) Nuclear pharmacies shall maintain records of acquisition and disposition of all radioactive drugs in accordance with rules and regulations of the United States Nuclear Regulatory Commission.

(e) The immediate outer container of a radioactive drug to be dispensed shall be labeled with the following:

1. The standard radiation symbol;
2. The words, ‘‘CAUTION—RADIOACTIVE MATERIAL’’;
3. The radionuclide;
4. The chemical form;
5. The amount of radioactive material contained in millicuries or microcuries;
6. If a liquid, the volume in milliliters;
7. The requested calibration time for the radioactivity contained;
8. The name, address, and telephone number of the nuclear pharmacy;
9. The prescription number; and
10. The date and patient’s name, if available.

(f) The immediate container shall be labeled with the following:

1. The standard radiation symbol;
2. The words, ‘‘CAUTION—RADIOACTIVE MATERIAL’’;
3. The name of the radiopharmaceutical.

(g) Nuclear pharmacies shall only dispense radiopharmaceuticals which comply with acceptable professional standards of radiopharmaceutical quality assurance.

(h) A nuclear pharmacist may transfer to authorized persons and United States Nuclear Regulatory Commission licensed medical practitioners radioactive materials not intended for drug use, in accordance with the regulations of the United States Nuclear Regulatory Commission or its successor. A nuclear pharmacy may furnish radiopharmaceuticals to these practitioners for patient use.

(i) Nuclear pharmacies shall comply with all applicable laws and regulations of Federal and State agencies including those laws and regulations governing non-radioactive drugs. For nuclear pharmacies handling radiopharmaceuticals exclusively, the Board of Pharmacy may waive rules pertaining to pharmacy permits for nonradiopharmaceuticals which requirements do not pertain to the practice of nuclear pharmacy.

(j) Radioactive drugs are to be dispensed only upon a non-refillable prescription order from a United States Nuclear Regulatory Commission licensed medical practitioner (or the designated agent) authorized to possess, use and administer radiopharmaceuticals.

(k) Prescription orders for delivery of radioactive drugs for use in the medical practice of a United States Nuclear Regulatory Commission licensed medical practitioner may be placed on a telephone answering and recording device, only if the practitioner (or the designated agent) is identified in such a manner that is clearly recognized by the nuclear pharmacist dispensing the radioactive drug.

(*l*) A qualified nuclear pharmacist shall have the authority to delegate to any qualified and properly trained person or persons, acting under his or her immediate personal supervision, any nuclear pharmacy act which a reasonable and prudent pharmacist would find is within the scope of sound pharmaceutical judgment to delegate. Such delegation may only occur if, in the professional opinion of the qualified nuclear pharmacist, the act may be properly and safely performed by the person to whom the pharmacy act is delegated. The delegated act may only be performed in its customary manner, not in violation of other statutes. The person to whom a nuclear pharmacy act is delegated shall not hold himself or herself out to the public being authorized to practice pharmacy.

13:39–12.3 General requirements for a nuclear pharmacist

(a) A qualified nuclear pharmacist shall meet the following requirements:

1. He or she is a pharmacist licensed to practice in the State of New Jersey; and
2. He or she meets minimal standards of training and experience in the handling of radioactive materials in accordance with the requirements of the United States Nuclear Regulatory Commission or its successor and the State of New Jersey Bureau of Radiation Protection.

13:39–12.4 Minimum requirements for space, equipment, supplies, and library

(a) Each nuclear pharmacy must meet the following requirements for space:

1. The area for the storage, compounding and dispensing of radioactive drugs shall be completely separate from pharmacy areas for nonradioactive drugs;
2. Hot lab and storage area shall be a minimum of 120 square feet; and
3. The compounding and dispensing area shall be a minimum of 300 square feet.

(b) Each nuclear pharmacy shall be equipped with at least the following items of equipment:

1. Dose calibrator;
2. Refrigerator;

3. Drawing station;
4. Well scintillation counter;
5. Microscope;
6. Chromatographic apparatus or comparable means of effectively assuring tagging efficiency;
7. Radiation survey equipment of the appropriate type and calibration to detect quantities of radioactive materials as prescribed in the appropriate radioactive material licenses; and
8. Other equipment deemed necessary for radiopharmaceutical quality control for products compounded or dispensed as may be determined by the United States Nuclear Regulatory Commission or its successor and the State of New Jersey Bureau of Radiation Protection.

(c) Each nuclear pharmacy shall have on the premises the following, upto- date reference books:

1. An up-to-date, comprehensive pharmaceutical reference text(s) and suitable reference texts encompassing the general practice of pharmacy, drug interactions, drug product composition and patient counseling. Unabridged computerized versions of these reference texts shall be acceptable;
2. State statutes and rules relating to pharmacy;
3. State and Federal regulations governing the use of applicable radioactive materials; and
4. Text relating to the practice of nuclear pharmacy and radiation safety.

13:39–12.5 Quality control

The holder of a nuclear pharmacy permit shall be responsible for the radioactive quality control of all drugs, including biologicals, dispensed or manufactured. Radioactive pharmaceutical quality controls include, but are not limited to, the carrying out and interpretation of data resulting from chemical, biological and physical tests on potentially radioactive pharmaceuticals to determine the suitability for use in humans and other animals, including internal test assessment and authentication of product history.

CHAPTER 45C UNIFORM REGULATIONS

SUBCHAPTER 1. LICENSEE DUTY TO COOPERATE AND TO COMPLY WITH BOARD ORDERS

13:45C–1.1 Applicability, scope and definitions

(a) This subchapter shall apply to all licensees of any board, committee or sub-unit within the Division of Consumer Affairs.

(b) For the purpose of this subchapter, ''licensee'' shall mean any licensee, permittee, certificate holder or registrant of:

1. The Division of Consumer Affairs;
2. Any professional or occupational licensing board within the Office of Professional/Occupational Boards and any committee, or other subunit of a board or committee located within the Division;
3. The Office of Consumer Protection; or
4. The Legalized Games of Chance Control Commission.

13:45C–1.2 Licensee's duty to cooperate in investigative inquiries

(a) A licensee shall cooperate in any inquiry, inspection or investigation conducted by, or on behalf of, a board, the Director or the licensee's licensing agency into a licensee's conduct, fitness or capacity to engage in a licensed profession or occupation where said inquiry is intended to evaluate such conduct, fitness or capacity for compliance with applicable statutory or regulatory provisions.

(b) A licensee's failure to cooperate, absent good cause or *bona fide* claim of a privilege not identified in N.J.A.C. 13:45C–1.5 as unavailable, may be deemed by the board, the Director, or the licensing agency to constitute professional or occupational misconduct within the meaning of N.J.S.A. 45:1–21(e) or the agency's enabling act and thus subject a licensee to disciplinary action pursuant to N.J.S.A. 45:1–21(h) or the agency's enabling act.

13:45C–1.3 Specific conduct deemed failure to cooperate

(a) The following conduct by a licensee may be deemed a failure to cooperate and, therefore, professional or occupational misconduct and grounds for suspension or revocation of licensure:

1. The failure to timely respond to an inquiry to provide information in response to a complaint received concerning licensee conduct;
2. The failure to timely provide records related to licensee conduct;
3. The failure to attend any scheduled proceeding at which the licensee's appearance is directed. In the event that a licensee elects to retain counsel for the purpose of representation in any such proceeding, it shall be the licensee's responsibility to do so in a timely fashion. The failure of a licensee to retain counsel, absent a showing of good cause therefor, shall not cause an adjournment of the proceeding;
4. The failure to timely respond or to provide information requested pursuant to a demand under N.J.S.A. 45:1–18 or other applicable law or to provide access to any premises from which a licensed profession or occupation is conducted. Included within this paragraph shall be the

failure to respond to any demand for statement or report under oath, the failure to permit the examination of any goods, ware or item used in the rendition of the professional or occupational service and the failure to grant access to records, books or other documents utilized in the practice of the occupation or profession;

5. The failure to answer any question pertinent to inquiry made pursuant to N.J.S.A. 45:1–18 or other applicable law unless the response to said question is subject to a *bona fide* claim of privilege;

6. The failure to make proper and timely response by way of appearance or production of documents to any subpoena issued pursuant to N.J.S.A. 45:1–18 or as may otherwise be provided by law; or

7. The failure to provide to the Board, the Director or the licensing agency timely notice of any change of address from that which appears on the licensee's most recent license renewal or application.

13:45C–1.4 Failure to comply with Board orders as professional or occupational misconduct

The failure of a licensee to comply with an order duly entered and served upon the licensee or of which the licensee has knowledge shall be deemed professional or occupational misconduct.

13:45C–1.5 Unavailability of privileges in investigative or disciplinary proceedings

(a) In any investigative inquiry conducted pursuant to N.J.S.A. 45:1–18 or in any disciplinary proceeding conducted pursuant to N.J.S.A. 45:1–21, or as may otherwise be authorized by law, the physician-patient privilege, psychologist-patient privilege, marriage and family therapist-client privilege, professional counselor-client privilege, associate counselor-client privilege, social worker-client privilege and the alcohol and drug counselor-client privilege shall be unavailable.

(b) Any statements or records otherwise subject to a claim of the stated privileges which may be obtained by the Board, its agent or the Attorney General pursuant to N.J.S.A. 45:1–18 shall remain confidential and shall not be disclosed unless so ordered by a court of competent jurisdiction, the appropriate licensing board or the Office of Administrative Law in a contested case.

13:45C–1.6 Maintenance of and access to statements, records or other information that is subject to a privilege declared unavailable

(a) Any statements, records or other information which may be subject to any privilege declared unavailable in this subchapter shall be maintained in a secure place and manner by:

1. The evidence custodian within the Division of Consumer Affairs, Enforcement Bureau;

2. The professional or occupational licensing board and the committee or other subunit of a board or committee located within the Division which has a direct connection with, or a need for access to, the matter to which the statements, records or other information pertain; or

3. A Deputy Attorney General.

(b) Except as may be otherwise ordered as provided in the subchapter, access to statements, records or other information shall be afforded only to employees of the Attorney General, the Enforcement Bureau, or the Board or other subunit of the Division having a direct connection with, or a need for access to, the matter to which the statement, records or other information pertain.

(c) The statements, records or other information shall be retained only for the period of time during which an investigation remains open or until the completion of all administrative or judicial proceedings relating thereto, at which time they shall be returned to the licensee or other person from whom they were obtained. In the absence of such licensee or other person, the statements, records or other information shall be returned to the patient, where appropriate.